UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

PLAINTIFF UNDER SEAL	)	Case No. 3-20- 0309
	)	
	)	
v.	)	**FILED BY HAND**
	)	
	)	**FILED UNDER SEAL**
DEFENDANT UNDER SEAL	)	
	)	**JURY TRIAL DEMANDED**
	)	

COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS
UNDER 31 U.S.C. §§ 3729 *ET SEQ.*

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

UNITED STATES OF AMERICA, State of TENNESSEE, *ex rel.* KRISTA NICHOLSON, Plaintiff/Relator, v. CLARKSVILLE PAIN INSTITUTE; PAIN INSTITUTE OF NASHVILLE, PLC; MICHAEL COX; DEBBIE COX; JOHN C. PRICHARD, Pharm.D.; PHARMACY SOLUTIONS, LLC; JOHN L. STANTON, M.D.; and JOHN L STANTON, MD, P.C., Defendants.	Civil Action No. 3-20- 0309 **COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS UNDER 31 U.S.C. §§ 3729 *ET SEQ.* AND ANALOGOUS STATE LAWS** **FILED BY HAND** **FILED UNDER SEAL**

I. NATURE OF ACTION

1. Relator Krista Nicholson ("Relator") brings this action under:

   a. 31 U.S.C. § 3730(b), the *qui tam* provision of the federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*;

   b. Tenn. Code Ann. § 4-18-104(c)(1), the *qui tam* provision of Tennessee's False Claims Act ("TFCA"), Tenn. Code Ann. §§ 4-18-101 *et seq.*;

   c. Tenn. Code Ann. § 71-5-182(b)(1), the *qui tam* provision of Tennessee's Medicaid False Claims Act ("TMFCA"), Tenn. Code Ann. §§ 71-5-182 *et seq.*;

   d. 31 U.S.C. § 3730(h), the anti-retaliation provision of the FCA;

   e. Tenn. Code Ann. § 4-18-105, the anti-retaliation provision of the TFCA;

   f. Tenn. Code Ann. § 71-5-183(g), the anti-retaliation provision of the TMFCA; and

   g. Tenn. Code Ann. § 50-1-304, the Tennessee Public Protection Act ("TPPA").

2. This action seeks to recover damages and civil penalties from Defendants on behalf of the United States of America and the State of Tennessee.

3. There are four intertwined groups of Defendants:

   a. First, and at the center of this scheme, are the "Clinic Defendants" comprised of the Clarksville Pain Institute ("CPI") and the Pain Institute of Nashville, PLC ("PIN"), which are both owned by Michael Cox and Debbie Cox, husband and wife. As detailed later in the Complaint, CPI and PIN registered multiple overlapping d/b/a names, and it appears that CPI acted as the umbrella company for the Cox's pain clinic, pharmacy, and lab operations through 2018, and then in 2019 the businesses began operating under the PIN umbrella.

   b. Second, are the "Pharmacy Defendants" comprised of: John C. Prichard, Pharm.D., who owns Pharmacy Solutions, LLC, which has registered the d/b/a "Medsource Scripts" and the d/b/a "Cox Pharmacy"; and CPI, which registered the d/b/a "Cox Family Pharmacy." All of these entities and d/b/a's claim to be doing pharmacy

business at the same Clarksville location, which primarily fills prescriptions for the two pain clinics.

c. Third, are the "Prescribing Defendants" comprised of John L. Stanton, M.D. and his practice John L Stanton, MD, P.C., which directly prescribed medications, as well as CPI and PIN, whose employee Medical Assistants and Physician Assistants also wrote prescriptions under the direction and/or supervision of Dr. Stanton.

d. Fourth, are the "Lab Defendants" comprised of and John L Stanton, MD, P.C. and PIN, both of which have clinical physician office labs registered at the Clarksville location.

The foregoing persons and entities are collectively referred to as the "Defendants."

4. Defendants coordinate their efforts to provide pain management services, clinical testing, prescription medications, steroid injections, and back braces to patients who are beneficiaries of a variety of federal and state healthcare programs described below ("Government Healthcare Programs"). For many years, and since at least January 1, 2014, Defendants obtained public funds to which they were not entitled through multiple knowing and material violations of the FCA, the TFCA, and the TMFCA, predicated on billing for medically unnecessary services and/or billing for services tainted by violations of the Medicare-Medicaid Anti-Kickback Statute and/or the Stark law.

5. Specifically, the two pain clinics typically prescribed for their patients some type of opioid pain medication, which was dispensed and billed by the "in-house" pharmacy located in an unmarked adjacent suite and owned by CPI (in turn owned by Michael and Debbie Cox) and/or Pharmacy Solutions, LLC (in turn owned by John C. Prichard).

6. CPI and PIN, however, then used their patients' addiction to opioids as leverage to compel their compliance with three types of tests and at least two of what they called "adjunct therapies," all of which were provided "in-house" and were motivated by greed rather than medical necessity.

7. As to the tests, first the pain clinics routinely administered allergy tests to all patients who consented and put the same unfounded diagnosis in the chart of each patient to justify billing for the tests. The pain clinics also routinely administered and billed for a psychological evaluation that, even when filled out by the patient rather than the staff, was not used for any purpose. The pain clinics also routinely administered urine drug screening tests to all patients, and more often than medically indicated. These tests were processed at the adjacent lab owned by CPI and/or John L. Stanton, MD, P.C.

8. As to the "adjunct therapies," these included steroid and trigger point injections administered by Dr. Stanton, compounded pain creams supplied by the secret pharmacy next door, and back braces supplied (and directly billed by) Dr. Stanton.

9. The clinics enforced their "adjunct therapy" business model by reducing or withholding a patient's opioid pain medication if the patient did not follow through with a therapy, such as by missing an appointment for a steroid injection.

10. In short, the clinics exploited the addictive nature of their primary opioid therapy to create a billing mill for medically unnecessary tests and "adjunct" therapies, which financially benefitted not only the clinics, but also the owners of the pharmacy and the lab, as well as Dr. Stanton personally.

11. Dr. Stanton, who was the only licensed physician providing oversight at the clinics, profited not only from the lab's billings and his services administering steroid injections, but also by directly billing for back braces. When Relator asked him why he was working at a pain clinic rather than continuing as an orthopedic surgeon, he quipped that he could work 60 hours/week as a surgeon, or he could make "quadruple" that by working just a couple days a week at the Cox's pain clinics.

12. As a result of the above scheme, the Clinic Defendants and the Lab Defendants billed Government Healthcare Programs for, and instituted policies to maximize profits through, medically unnecessary and excessive tests, including urine drug tests, psychological tests, and allergy tests.

13. The Clinic Defendants and/or Dr. Stanton also falsely billed Government Healthcare Programs for medically unnecessary injection procedures that were not properly payable.

14. The Prescribing Defendants and/or Dr. Stanton caused, and the Pharmacy Defendants submitted, false billings to Government Healthcare Programs for compounded pain medications that were not medically necessary.

15. Relator worked at CPI in a variety of positions and obtained independent, firsthand knowledge of Defendants' schemes. Relator's 2018 W-2 form lists CPI as her employer. Her 2019 W-2 form lists PIN as her employer. Due to the ambiguity as to the identity of Relator's actual employer, and for purposes of this Complaint, her employer is identified as both CPI and PIN.

16. Relator reported the fraudulent conduct to a company executive, but her reports were ignored.

17. Instead of appreciating Relator for bringing forward her concerns (and because she did so), Defendants CPI and PIN retaliated against her and fired her.

18. Relator is not aware that Defendants ever disclosed or corrected the overpayments they received as a result of their false billings.

19. Relator alleges that Defendants' misconduct began over six years ago, was widespread, and, upon information and belief, continues to the present.

II. JURISDICTION AND VENUE

20. The Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1331, because the case presents claims under a federal statute. Venue is proper in this Court because, among other things, Defendants transact business in this District, and Defendants engaged in wrongdoing in this District. The claims brought on behalf of the United States and the State of Tennessee seek recovery of federal and state funds expended by federal and state health care programs.

21. The Court has original jurisdiction of the State law claims pursuant to 28 U.S.C. § 1367 and 31 U.S.C. § 3732(b), because this action is brought under the laws of the State of

Tennessee for the recovery of funds paid by the State arising from the same scheme and for violations of the TFCA, the TMFCA, and the TPPA. Moreover, with respect to State law claims arising from billings to Medicaid, the State law claims arise from exactly the same transactions or occurrences brought under 31 U.S.C. § 3730 to recover the United States' share of those Medicaid payments.

22. The Court has personal jurisdiction over Defendants, and venue is proper in this District under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and (c). Defendants reside in or operate in Tennessee, Defendants transact substantial business within this District, and acts proscribed by 31 U.S.C. § 3729, including a substantial part of the events and omissions giving rise to the claims alleged, occurred in this District.

23. Relator is aware of no statutorily relevant public disclosure of the allegations or transactions forming the core elements of the Counts against Defendants. Even if such a disclosure had occurred, Relator is the "original source" of the allegations in this Complaint as that term is used in the FCA, the TFCA, and the TMFCA. During her employment and independent investigation, Relator acquired material, direct, independent, and non-public knowledge of the information on which the allegations in this Complaint are based, and she voluntarily and in good faith provided this information to the United States Government and the State of Tennessee before filing this action.

IV. PARTIES

A. Relator Krista Nicholson

24. Relator Nicholson has formal training and certification as an EMT. She worked at CPI from August 22, 2018 through April 18, 2019. During her employment, Relator held several positions, including Medical Assistant, Injection/Fluoroscopy Technician, Urine Drug Screen Technician, Receptionist, and Prior Authorization Coordinator.

B. Clarksville Pain Institute and its Affiliated Pharmacies

25. According to filings with the Tennessee Secretary of State, Defendant CPI is a Tennessee domestic limited-liability company formed on January 1, 2012.

26. The company's filing status is listed as active.

27. The registered agent is Debbie F. Cox at 1849 Madison Street, Suite F, Clarksville, TN 37043-4903. This address is also the company's principal address and mailing address.

C. Pain Institute of Nashville, PLC

28. According to filings with the Tennessee Secretary of State, Defendant PIN is a Tennessee domestic limited-liability company formed on February 15, 2017.

29. The company's filing status is listed as Active.

30. The registered agent is Michael Cox at 1849 Madison Street, Suite F, Clarksville, TN 37043-4903. This address is also the company's principal address and mailing address.

31. According to Defendant PIN's operating agreement, Debbie F. Cox is president (with 99% interest), Michael Cox is Secretary (non-member), and John L. Stanton, M.D. is Medical Director (with 1% interest).

D. Michael Cox

32. Michael Cox is the CEO and CFO of CPI, Cox Pharmacy, and Cox Realty. According to his online biography, Mr. Cox has a B.S. in Business Administration from Tusculum College. As noted above, Mr. Cox is the registered agent of PIN. Mr. Cox controls finances and paperwork for CPI and PIN.

E. Debbie Cox

33. According to her online biography, Mrs. Cox is the owner of CPI and is also a Certified Nurse Anesthetist.

F. John L. Stanton, M.D. (an Individual) and John L Stanton, MD, P.C. (a Tennessee Professional Corporation)

34. Defendant John L. Stanton, M.D., is or was affiliated with the following facilities/clinics: (a) CPI (including the Pain Institute of Springfield/White House location); (b) Riverside Spine & Physical Medicine; (c) The Bone & Joint Group; (d) The Joint & Spine Center; and (e) Gateway Medical Associates.

35. Dr. Stanton is also the Medical Director at Hayes Endocrine & Diabetes Center in Nashville, Tennessee.

36. According to filings with the Tennessee Secretary of State, Dr. Stanton is the registered agent of John L. Stanton, MD P.C. (a professional corporation located at 980 Professional Park Drive, Suite A, Clarksville, Tennessee).

37. John L. Stanton, MD P.C. has a certified "physician office" clinical testing lab located at 1849 Madison Street, Suite D, Clarksville, TN 37043, which is adjacent to the Cox's primary pain clinic, lab, and pharmacy operations.

G. John C. Prichard (an individual) and Pharmacy Solutions, LLC

38. Defendant John C. Prichard, Pharm.D., is held out as the Director of the Cox Family Pharmacy, located at 1849 Madison Street, Suite D, Clarksville, TN 37043.

39. Pharmacy Solutions, LLC is a Tennessee limited liability company with its principal place of business at located at 1849 Madison Street, Suite D, Clarksville, TN, where it operates under the assumed names of Cox Pharmacy and Medsource Scripts.

V. APPLICABLE STATUTES AND REGULATIONS

A. The False Claims Acts

40. The FCA, the TFCA, and the TMFCA are, in general, *in pari materia* for each other. Thus, Relator here frames the law using the language of the FCA. However, in the separate Counts and Requests for Relief as to the State of Tennessee, Relator uses the precise language of each respective statute.

41. The FCA makes it unlawful for any person to submit, directly or indirectly, false or fraudulent claims for payment to the Government. *See* 31 U.S.C. §§ 3729 *et seq.* Relator alleges liability primarily under four of the FCA's seven liability provisions.

42. First, the FCA's "presentment" provision, 31 U.S.C. § 3729(a)(1)(A), imposes liability when a defendant (a) made, or caused to be made, a claim, (b) that was false or fraudulent, (c) knowing of its falsity.

43. Second, the FCA's "false records or statements" provision, 31 U.S.C. § 3729(a)(1)(B), imposes liability when a defendant (a) made, used, or caused to be made or used, a record or statement, (b) that was knowingly false, and (c) that was material to a false or fraudulent claim.

44. Third, the FCA's "conspiracy" provision, 31 U.S.C. § 3729(a)(1)(C), imposes liability for conspiring to violate the FCA's presentment provision, the false records or statements provision, or the reverse false claims provision, discussed in the following paragraph.

45. Fourth, the FCA's "reverse false claims" provision, 31 U.S.C. § 3729(a)(1)(G), imposes liability when a defendant (a) "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government" or (b) "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government."

46. The "knowledge" element of the FCA is defined as (1) "actual knowledge of the [falsity of the] information"; (2) "deliberate ignorance of the truth or falsity of the information"; or (3) "reckless disregard of the truth or falsity of the information" provided to the Government. 31 U.S.C. § 3729(b)(1).

47. Under the FCA, the term "claim" means any request or demand for money, whether under a contract or otherwise, presented to an officer, employee, or agent of the United States. 31 U.S.C. § 3729(b)(2)(A)(i). A "claim" is also a request or demand for money made to a contractor or other recipient if (a) the money is to be spent or used on the Government's behalf or to advance a Government program or interest and (b) if the Government provides, has provided, or will reimburse such contractor or other recipient for any portion of the money requested or demanded. 31 U.S.C. § 3729(b)(2)(A)(ii).

48. The FCA defines the term "obligation" to mean an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment. 31 U.S.C. § 3729(b)(3).

49. The FCA defines "material" objectively, not subjectively, to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). The Supreme Court reaffirmed the natural tendency materiality test—even as to subsection (a)(1)(A), which does not explicitly use the term—and described a holistic approach to analyzing it. *See Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016).

50. Relator alleges that Defendants presented claims for payment to Government Healthcare Programs that were "false or fraudulent" because they sought reimbursement for medically unnecessary and excessive urine drug tests, psychological tests, allergy tests, and compounded pain medications and for medically unnecessary injection procedures that were not properly payable.

51. In addition, Defendants knew that they had over-billed, yet failed to self-disclose the misconduct to Government Healthcare Programs or to refund the excessively billed and paid amounts, all in violation of 31 U.S.C. § 3729(a)(1)(G). Defendant CPI knew of this misconduct at least since early 2019 when Relator notified it of its false billings to Government Healthcare Programs.

B. The Medicare/Medicaid Anti-Kickback Statute

52. The Medicare and Medicaid Patient Protection Act of 1987, also known as the federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), prohibits kickbacks in any "Federal health care program," defined as any program providing health benefits that is funded directly, in whole or in part by the United States Government, and any "State health care program." 42 U.S.C. § 1320a-7b(b)(2)(A) and (f). State health care programs include those approved under 42 U.S.C. §§ 1396 *et seq*. and child health plans approved under 42 U.S.C. §§ 1397aa *et seq.* They also include any programs receiving funds under or from an allotment to a State under 42 U.S.C. §§ 701 *et seq*. or 42 U.S.C. §§ 1396 *et seq*.

53. The AKS applies to all federal health care programs, except the Federal Employee Health Benefits Plan. These include, among others, Medicare, Medicaid, TRICARE, Indian Health

Services, and the Veterans Health Administration. All of these government-pay health care programs require every provider or supplier to ensure compliance with federal laws governing their services, including the AKS.

54. Violation of the AKS can result in the imposition of criminal penalties. 42 U.S.C. § 1320a-7b(a) and b) (violation constitutes a felony, punishable by up to ten years in prison and/or a fine of $100,000).

55. Since 2010, Congress has also removed any doubt as to the materiality of an AKS violation to liability under the FCA. The Patient Protection and Affordable Care Act ("PPACA") specifically links violations of the AKS to the FCA. It amended the AKS to provide that "items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]." 42 U.S.C. § 1320a-7b(g).

56. The PPACA also amended the intent requirement to clarify that, just as with violations of the FCA, violations of the federal anti-kickback provisions may occur even if an individual "does not have actual knowledge" or "specific intent to commit a violation." *Id.* at § 6402(h).

57. The purpose of the AKS is to ensure that patient care is not compromised by improper influence from the health care industry. "The Federal anti-kickback law's main purpose is to protect patients and the federal health care programs from fraud and abuse by curtailing the corrupting influence of money on health care decisions." (OIG Fact Sheet, November 1999, Federal Anti-Kickback Law and Regulatory Safe Harbors.)

58. Under the AKS, it is illegal (a felony) to knowingly and willfully offer or pay "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person" to induce that person "to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2).

59. The AKS provides certain "safe harbors" that allow medical providers to compensate physicians for activities that meet particular requirements. 42 U.S.C. § 1320a-7b(b)(3); 42 C.F.R. § 1001.952. In the present case, none of the safe harbors applies.

60. Strict compliance with the "safe harbor" mandates is required. Many courts have held that, regardless of the appearance of compliance, the AKS is violated even if just one purpose of the conduct is to induce sales. *See, e.g.*, *United States v. Hong*, 938 F.3d 1040, 1048 (9th Cir. 2019); *Dhaliwal v. Salix Pharm.*, Ltd., 752 F. App'x 99, 100 (2d Cir. 2019); *Guilfoile v. Shields*, 913 F.3d 178, 189 (1st Cir. 2019).

C. The Stark Law

61. The Stark Law, 42 U.S.C. § 1395nn, is also known as the Physician Self-Referral Law. Implementing regulations are codified at 42 C.F.R. §§ 411.350 *et. seq.* The Stark Law prohibits submission by an entity providing healthcare items or services of claims for payment to Medicare or Medicaid based on patient referrals from physicians having a "financial relationship" (as defined in the statute) with the referring entity.

62. The regulations implementing Stark expressly make it illegal for anyone to receive federal payment for a healthcare service that was performed "pursuant to a prohibited referral" and requires such person to "refund all collected amounts on a timely basis." 42 C.F.R. § 411.353.

63. Congress enacted the Stark Law in two parts, commonly known as Stark I and Stark II. Enacted in 1989, Stark I applied to referrals of Medicare patients for clinical laboratory services made on or after January 1, 1992 by physicians with a prohibited financial relationship with the clinical lab provider. Omnibus Budget Reconciliation Act of 1989, P.L. 101-239, § 6204.

64. In 1993, Congress extended the Stark Law (Stark II) to referrals for ten additional designated health services (DHS) effective January 1, 1995, including (1) inpatient and outpatient hospital services; (2) physical therapy; (3) occupational therapy; (4) radiology; (5) radiation therapy (services and supplies); (6) durable medical equipment and supplies, (7) parenteral and enteral nutrients, equipment, and supplies; (8) prosthetics, orthotics, and prosthetic devices and

supplies; (9) outpatient prescription drugs; and (10) home health services. 42 U.S.C. § 1395nn(h)(6).

65. The Stark statute defines "referral" as "the request or establishment of a plan of care by a physician which includes the provision of the designated health service." 42 U.S.C. § 1395nn(h)(5)(B). The implementing regulations also define "referral" as, among other things, "a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare. . . ." 42 C.F.R. § 411.351. A "referring physician" is defined as "a physician who makes a referral as defined in this section or who directs another person or entity to make a referral or who controls referrals made to another person or entity." *Id.*

66. Stark expressly prohibits any entity from presenting or causing the presenting of any claim resulting from a referral from a physician who has a financial relationship with the entity, unless that relationship fits into one of the specific exceptions in the statute. For example, certain ownership interests in publicly-traded securities and in hospital entities are excepted. *See* 42 U.S.C. § 1395nn(d).

67. The Stark law was intended to prevent physicians from profiting (actually or potentially) from their own referrals. The Stark statute prospectively prohibits relationships that have been demonstrated to encourage over-utilization. It is a strict-liability statute.

68. Any remuneration flowing between entities and physicians must be at fair market value for actual and necessary items furnished or services rendered based on an arms-length transaction and should not take into account, directly or indirectly, the value or volume of any past or future referrals or other business generated between the parties.

69. Whenever a physician receives compensation for services furnished to an entity pursuant to a bona fide employment arrangement with the entity, the physician is deemed to have a "financial relationship" with the entity under the Stark law in the form of a "compensation arrangement." An entity-employed medical director would maintain such a financial relationship regardless of the amount of compensation received or the manner in which it was calculated. 42 U.S.C. § 1395nn(h)(1); 42 C.F.R. §§ 411.354(a), 411.354(c).

70. Stark includes an exception protecting compensation to be paid pursuant to such employment arrangements 42 U.S.C. § 1395nn(e)(2); 42 C.F.R. § 411.357(c). In order to qualify for protection under this exception, the arrangement must satisfy the following requirements:

a. The employment must be for identifiable services but does not have to be memorialized.

b. The amount of compensation paid to the physician must be consistent with fair market value of the services furnished and must not be determined in a manner that takes into account the volume or value of Medicare referrals generated by the physician for the entity (excluding referrals for professional services personally performed by the referring physician).

c. The remuneration paid to the physician must be reasonable even if no Medicare referrals were made to the entity.

71. "The Stark Law is intended to prevent 'overutilization of services by physicians who [stand] to profit from referring patients to facilities or entities in which they have a financial interest.'" *United States ex. rel. Drakeford v. Tuomey*, 675 F.3d 394, 373 (4th Cir. 2012) (citation omitted). The Stark Law is a strict liability statute with no scienter requirement. Any amounts reimbursed by Medicare for services furnished in violation of the Stark Law must be repaid. 42 U.S.C. § 1395nn(g)(1); 42 C.F.R § 411.353(d); *Drakeford*, 675 F.3d at 397-98; *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008) ("*Rogan II*").

72. Once the United States (or a relator suing on its behalf) has established the existence of a financial relationship and DHS referrals, defendants bear the burden of proving that the arrangements at issue meet all the requirements of an applicable exception to the statute. *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 95 (3d Cir. 2009); *accord Drakeford*, 675 F.3d at 405; *Rogan*, 459 F. Supp. 2d 692, 716 (N.D. Ill. 2006) ("*Rogan I*").

D. Government Healthcare Programs Affected by Defendants' Misconduct

1. Medicare

a. Generally

73. Title XVIII of the Social Security Act ("Medicare") is a federally subsidized health insurance system for persons who are eligible based on age (over 65), disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426-1, 426A.

74. HHS is responsible for the administration and supervision of the Medicare program. CMS, formerly known as the Health Care Financing Agency ("HCFA"), is an agency of HHS and is directly responsible for the administration of the Medicare program.

75. CMS contracts with private contractors referred to as "fiscal intermediaries," "carriers," and Medicare Administrative Contractors ("MACs"), to act as agents in reviewing and paying claims submitted by health care providers. 42 U.S.C. §§ 1395h, 1395u; 42 C.F.R. §§ 421.3, 421.100, 421.104. Fiscal intermediaries, typically insurance companies, are responsible for processing and paying claims for reimbursement.

76. Like Medicaid, Medicare's general coverage parameters only include items that are "provided economically and only when, and to the extent, medically necessary . . ." 42 U.S.C. § 1320c-5(a)(1). It also excludes goods and services that are not medically "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k).

77. To seek reimbursement from Medicare and the other Government Healthcare Programs described below, a health care provider must obtain an NPI number. The provider also must submit an enrollment application.

78. Medicare is divided into four parts with separate coverage authorities: Medicare Part A (hospital insurance); Medicare Part B (medical insurance); Medicare Part C (Medicare Advantage); and Medicare Part D (prescription drug coverage). In this action, only Medicare Part B and Part D are relevant.

b. Medicare Part B

79. Medicare Part B is a voluntary subscription program of supplementary medical insurance covering outpatient care, including physician services and ancillary services. 42 U.S.C. § 1395k.

80. The Clinic Defendants and the Lab Defendants billed Medicare under Part B, which covers certain medical services furnished by physicians and other providers and suppliers. 42 U.S.C. § 1395k(a)(2)(B).

81. Typically, physicians are compensated for the services they provide Medicare patients on a fee-for-service basis as determined by Medicare's fee schedule. 42 U.S.C. § 1395w-4. To obtain compensation, physicians must deliver a compensable service, certify that the service was medically necessary for the health of the patient, certify that the service was personally furnished by the physician (or under his or her immediate supervision), and determine the appropriate diagnosis and procedure code to describe the problem and service for billing.

82. The Medicare statute requires that each request for payment or bill submitted for an item or service payable under Medicare Part B include the name and unique physician identification number for the referring physician. 42 U.S.C. § 1395l(q)(1).

83. To obtain Medicare and Medicaid reimbursement for certain outpatient items or services, providers and suppliers submit a claim form known as the CMS 1500 form ("CMS 1500") or its electronic equivalent known as the 837P form. Among the information the provider or supplier includes on a CMS 1500 or 837P form are certain five-digit codes, including Current Procedural Terminology Codes ("CPT codes") and Healthcare Common Procedure Coding System ("HCPCS") Level II codes, that identify the services rendered and for which reimbursement is sought, and the unique billing identification number (NPI) of the "rendering provider" and the "referring provider or other source."

84. Medicare only pays for Part B services that are actually rendered and are reasonable and medically necessary. 42 U.S.C. § 1395y(a). Part B providers also must certify that services are medically necessary. 42 C.F.R. § 424.24(g)(1).

85. Medicare requires proper and complete documentation of the services rendered to beneficiaries. 42 U.S.C. § 1395l(e).

86. From 2011 through February 25, 2018, Cahaba Government Benefit Administrators, LLC ("Cahaba") was the MAC that administered Medicare Part B claims in

Tennessee. As of February 26, 2018, Palmetto Government Benefit Administrator, LLC ("Palmetto") became the MAC for Tennessee. Because the Clinic Defendants and the Lab Defendants performed all of their tests and services at facilities in Tennessee, they submitted all claims to these Medicare contractors.

c. Ineligible Part B Claims Are Actionable Under the FCA

87. A provider must enroll in the Medicare program to receive Medicare reimbursement for covered services provided to eligible beneficiaries. To participate in the Medicare program, a provider must file a provider agreement with the Secretary of HHS ("the Secretary"). 42 U.S.C. § 1395cc. The provider agreement requires compliance with the requirements that the Secretary deems necessary for participation in the program. *Id.*

88. Among other things, participating providers are prohibited from making false statements or representations of material facts concerning payment requests. 42 U.S.C. §§ 1320a-7b(a)(1) and (2); 42 U.S.C. § 1320a-7a(1); 42 C.F.R. § 1001.101(a). Providers are also required to know the information contained in HHS, CMS, and fiscal intermediary notices, including manual issuances, bulletins, and other written guides and directives. 42 C.F.R. § 411.406.

89. The enrollment application includes a certification statement requiring the enrolling provider to certify the provider's adherence to a list of requirements, including, among others, the following:

a. Familiarity with and agreement to abide by applicable Medicare or other federal health care program laws, regulations, and program instructions, which are available through the Medicare Contractor.

b. Understanding that payment of a claim by Medicare or other federal health care programs is conditioned on the claim and the underlying transaction complying with such laws, regulations and program instructions (including the anti-kickback statute and the Stark law), and on a provider/supplier complying with any applicable conditions of participation in any federal health care program.

c. Agreement not to knowingly present or cause to be presented a false or fraudulent claim for payment by the Medicare or other federal health care programs and not to submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

90. At all times material to this action, the Clinic Defendants and the Lab Defendants had signed a Medicare enrollment application and/or had entered a Medicare provider agreement as described above.

91. Debbie Cox and Dr. Stanton signed an enrollment application (Form CMS 855S) dated October 20, 2018, certifying that "[m]y signature legally and financially binds this supplier to the laws, regulations, and program instructions of the Medicare program."

92. By signing the Form 855S, Debbie Cox and Dr. Stanton also expressly agreed to abide by applicable Medicare laws, regulations, and program instructions, which they acknowledged are available through the Medicare contractor. Debbie Cox and Dr. Stanton also certified that they understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the AKS and the Stark law) and on their own compliance with all applicable conditions of participation in Medicare.

93. Following enrollment, physicians and other health care providers who provide services to Medicare beneficiaries submit to the appropriate Medicare fiscal intermediary a claim for reimbursement through a CMS 1500. Regulations adopted by CMS require that a provider's services and procedures must be entered onto a CMS 1500 by using procedure codes published by the American Medical Association, known as the Physicians' Current Procedural Terminology ("CPT"). 45 C.F.R. § 162.1002. Providers submit these claims for reimbursement by mail or electronically pursuant to an "Electronic Data Interchange (EDI) Enrollment Form" ("EDI Form") (and other documents) signed by the provider.

94. At all times material to this action, the Clinic Defendants and the Lab Defendants submitted, or caused to be submitted, Forms CMS 1500 by one or both of these methods.

95. Pursuant to the EDI Form, the provider, among other things, (a) certifies that it will submit claims that are accurate, complete, and truthful; (b) agrees that all claims are claims for payment under the Medicare program that will be paid from federal funds; and (c) agrees that falsifying or misrepresenting (or causing the falsification or misrepresentation of) any record or information relating to such claims violates applicable federal law. In addition, the electronic claims themselves contain a certification of accuracy and veracity. At all relevant times, the Clinic Defendants and the Lab Defendants had entered and were obligated by such an agreement.

96. Medicare relies upon provider certifications in paying claims for services.

97. Similarly, when enrolling to submit claims electronically, providers certify that they will submit claims that are "accurate, complete, and truthful."[1]

98. A participating provider must properly document in the patient's medical record the service or procedure performed. 42 C.F.R. § 431.107(b)(1).

99. Health care providers are prohibited from knowingly presenting or causing to be presented claims for items or services that the person knew or should have known were not medically necessary, or knew or should have known were false or fraudulent. 42 U.S.C. §§ 1320a-7a(a)(1); 1320a-7(b)(7) (permitting exclusion of providers for the foregoing violations).

100. A provider has a duty to familiarize itself with the statutes, regulations, and guidelines regarding coverage for the Medicare services it provides. *Heckler v. Cmty. Health Servs. of Crawford Cty., Inc.,* 467 U.S. 51, 64 (1984).

101. Because it is not feasible for the Medicare program, or its contractors, to review medical records corresponding to each of the millions of claims for payment it receives from providers, the program relies on providers to comply with Medicare requirements and to submit truthful and accurate certifications and claims.

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[1] *See* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS10164B.pdf (last visited February 5, 2020).

102. Generally, once a provider submits a CMS 1500, or the electronic equivalent, to the Medicare program, the claim is paid directly to the provider, in reliance on the foregoing certifications, without any review of supporting documentation, including medical records.

103. Using electronic and other means, the Clinic Defendants and the Lab Defendants routinely and knowingly submitted false claims, or caused false claims to be submitted, to the United States because the Clinic Defendants and the Lab Defendants knowingly billed Medicare or knowingly caused Medicare to be billed for beneficiaries who did not meet Medicare benefit eligibility requirements.

d. Medicare Part D

104. In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA"), Pub. L. 108-173, 117 Stat. 2066, which established a voluntary prescription drug benefit program for Medicare enrollees known as Medicare Part D. An individual is eligible to enroll in Medicare Part D if the individual lives in the service area of a Part D plan and is entitled to Medicare benefits under Medicare Part A or enrolled under Medicare Part B. 42 U.S.C. § 1395w-l01(a)(3)(A); 42 C.F.R. § 423.30(a).

105. Medicare Part D coverage is based on a private market model. Under Medicare Part D, Medicare contracts with private entities, known as Part D Plan "Sponsors," to administer prescription drug plans. A Part D Plan Sponsor may be either a prescription drug plan, a Medicare Advantage organization that offers a Medicare Advantage prescription drug plan, a Program of All-inclusive Care for the Elderly ("PACE") organization offering a PACE plan including qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage. 42 C.F.R. § 423.4.

106. The Clinic Defendants and the Lab Defendants caused the Pharmacy Defendants to bill Medicare under Part D.

107. The Pharmacy Defendants billed Medicare under Part D.

108. Medicare beneficiaries who wish to receive Part D benefits must enroll in a Part D Plan offered by a Part D Plan Sponsor. The Part D Sponsors are regulated and subsidized by CMS

pursuant to one-year, annually renewable contracts. Part D Sponsors, in turn, enter into subcontracts with pharmacies or other downstream entities to provide prescription drugs to the Medicare Part D beneficiaries enrolled in their plans.

109. Medicare Part D covers only drugs that are prescribed for a "medically accepted indication," which, in general, means a use that is (1) approved by the U.S. Food & Drug Administration ("FDA") under the Food Drug and Cosmetic Act, or (2) supported by one or more citations in one of the following compendia: American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information (or its successor), or DRUGDEX Information System (collectively, the "compendia"). *See* 42 U.S.C. §§ 1395w-102(e)(1), (e)(4), 1396r-8(g)(1)(B), (k)(6); 42 C.F.R. § 423.100.

110. With respect to compounded drugs, only the ingredients of the compound that are dispensed for a "medically accepted indication" are eligible for reimbursement under Medicare Part D. *See* Medicare Program; Medicare Prescription Drug Benefit; Final Rule, 70 Fed. Reg. 4,194 at 4,231–32 (Jan. 28, 2005).

111. When a pharmacy dispenses drugs to a Part D beneficiary, the pharmacy submits a claim electronically to the beneficiary's Part D Sponsor. The pharmacy receives reimbursement from the CMS-funded Part D Sponsor for the portion of the covered drug cost not paid by the Part D beneficiary at the point of sale. Sometimes a pharmacy benefit manager, or "PBM," serves as an intermediary between the Part D Sponsor and the pharmacy.

112. In general, the Part D Sponsor reimburses the pharmacy for compounded drugs based on a negotiated price for each covered ingredient based on common drug pricing benchmarks, including the average wholesale price, wholesale acquisition cost, or maximum allowable cost. The reimbursement amount also is based in part on the quantity of each covered ingredient in the compounded drug.

113. The Part D Sponsor is required to submit to CMS an electronic notification of the drug dispensing event, called the Prescription Drug Event ("PDE"), which contains data regarding the Medicare prescription drug claim, including the drug dispensed, the quantity dispensed,

whether the drug is a compound, the service provider that dispensed the drug, the prescriber, the patient, the amount paid to the pharmacy, the copayment amount, and whether the drug is covered under Medicare Part D.

114. Certain information in the PDE is derived from the representations that the pharmacy makes when it submits the reimbursement claim to a Medicare Part D Sponsor. These representations include the drug dispensed, the quantity dispensed, whether the drug was a compound, the service provider that dispensed the drug, the prescriber, and the patient.

115. Although the PDE record contains a field that indicates if a drug is a compound, the PDE record does not contain a route of administration field that indicates whether the compounded drug is intended for oral or topical use. Likewise, the PDE record does not contain a diagnosis code.

116. If the drug is a compounded drug containing multiple ingredients, the most expensive Part D ingredient in the compound is reported in the PDE record. In addition, the total quantity of all the ingredients in a compound is reported in the PDE record. Although the pharmacy submits the quantity of each individual ingredient to the Part D Sponsor to be used to determine the amount of Medicare reimbursement the Part D Sponsor pays to the pharmacy, the quantity of each individual ingredient in a compounded drug is not reported to CMS in the PDE record.

117. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program.

118. Generating and submitting PDE claims data is necessary for CMS to administer the Part D program and make payments to Part D Plan Sponsors to reimburse them for qualified prescription drug coverage that they provide to Medicare beneficiaries. Generating and submitting PDE data is a condition of payment for CMS's provision of Medicare funds to Part D Plan Sponsors. *See* 42 C.F.R. § 423.322.

119. CMS pays for Medicare beneficiaries' drugs through several payment mechanisms. First, Medicare pays a direct subsidy (a capitated payment) to the Part D Plan Sponsor in the form of advance monthly payments equal to the Part D Plan's standardized bid, risk adjusted for health status as provided in 42 C.F.R § 423.329(b), minus a monthly beneficiary premium as determined in 42 C.F.R. § 423.315(b). In other words, CMS pays a monthly sum to the Part D Plan Sponsor for each Part D beneficiary enrolled in the plan.

120. Second, CMS makes payments to the Part D Plan Sponsor for premium and cost-sharing subsidies on behalf of certain subsidy-eligible individuals as provided in 42 C.F.R. § 423.780 and 423.782. Cost-sharing subsidies for qualifying low-income individuals are called the Low-Income Subsidy ("LIS") and are documented and reconciled using PDE data submitted to CMS.

121. Third, CMS pays a reinsurance subsidy to the Part D Plan Sponsor which is equal to 80 percent of covered drug spending above an enrollee's catastrophic threshold. CMS uses the PDEs submitted by Part D plan Sponsors to ensure that Medicare is subsidizing 80 percent of the Part D beneficiaries' catastrophic coverage costs.

122. Fourth, the Medicare Part D program includes risk-sharing corridors, which seek to limit a plan's overall losses across all enrollees in the event that a plan's spending for benefits is higher than anticipated at the time that the plan submits its bid. After a reconciliation process conducted at the end of the year, CMS may have to pay additional amounts to a plan if the plan's losses exceed a certain threshold, or CMS may be entitled to recoup excess profits from a plan whose costs fell short of projections that formed the basis for the direct subsidy payment. This reconciliation process is based on information contained in the PDEs.

123. The payments made by CMS to the Part D Sponsor come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R. § 423.315(a).

2. Medicaid/TennCare

124. In 1965, Congress established the Grants to States for Medical Assistance Programs under Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w-2 ("Medicaid"). Medicaid provides medical and health-related assistance for society's neediest and most vulnerable individuals. Those eligible for Medicaid include pregnant women, children, and persons who are blind or suffer from other disabilities and who cannot afford the cost of health care. 42 U.S.C. § 1396d.

125. Medicaid is a joint federal-state health care program. 42 U.S.C. § 1396b. If a state elects to participate in the program, the costs of Medicaid are shared between the state and the federal government. 42 U.S.C. § 1396a(a)(2). In order to receive federal funding, a participating state must comply with requirements imposed by the Act and regulations promulgated thereunder.

126. Medicaid is administered at the federal level by the Secretary of the Department of Health and Human Services ("HHS"), an agency of the United States, through CMS, which promulgates regulations—including minimum coverage parameters.

127. Each state has its own Medicaid agency, which is responsible for developing CMS-approved programs, setting its own guidelines regarding eligibility and services, and administering claims.

128. The federal portion of Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). As a result, the federal matching funds range from 50-75%.

129. In this FCA action, the practical effect of Medicaid's dual funding mechanism is that the FCA will recover the FMAP of each affected claim submitted in any state or territory.

130. To qualify for these federal matching funds, each state Medicaid program must submit a plan to the Secretary of HHS for approval. *See* 42 C.F.R. § 430 Subpart B, and § 488.303.

131. Tennessee participates in the Medicaid program pursuant to Tenn. Code Ann. §§ 71-5-101 to 71-5-199. The federal government, through CMS, provides approximately 65% of the funds used by the Tennessee Medicaid program to provide medical assistance to persons enrolled in the Medicaid program.

132. In return for receipt of federal subsidies, Tennessee is required to administer its Medicaid program in conformity with a state plan that satisfies the requirements of the Act and accompanying regulations. 42 U.S.C. §§ 1396–1396w; Tenn. Code Ann. § 71-5-102. In Tennessee, the Department of Finance and Administration administers the state Medicaid program through TennCare. Tenn. Code Ann. § 71-5-104. TennCare operates as a special demonstration project authorized by the Secretary of Health and Human Services under the waiver authority conferred by 42 U.S.C. § 1315. The Department of Finance and Administration supervises TennCare's administration of medical assistance for eligible recipients. Tenn. Code Ann. § 71-5-105-107. The Department of Finance and Administration is also authorized to promulgate rules and regulations to carry out the purposes of TennCare. Tenn. Code Ann. §§ 71-5-124 to –134.

133. TennCare contracts with private managed care contractors ("MCCs") through contracts, known as Contractor Risk Agreements ("CRAs"), which must follow the requirements of 42 U.S.C. § 1395mm, along with any related federal rules and regulations. Tenn. Code Ann. § 71-5-128.

134. The MCCs contract directly with providers to provide health care services to eligible TennCare beneficiaries. Providers who have entered into such a contract with an MCC are known as Participating Providers. Tenn. Comp. R. & Regs. § 1200-13-13-.01(89). Pursuant to the CRAs, TennCare distributes the combined state and federal Medicaid funding to the MCCs, which then pay Participating Providers for treatment of TennCare beneficiaries. TennCare-eligible persons seeking medical assistance enroll in an MCC to receive health care services from a Participating Provider.

135. The administration and payment of claims submitted by providers is handled by each state Medicaid program, which then submits claims information to the federal government in order to obtain the requisite FMAP. As a result, each claim for payment submitted to Medicaid is both a "claim" for payment submitted directly to the relevant state, and a "claim" for payment submitted indirectly to the United States. The respective claim mechanisms are described below.

a. Medicaid "Claims" for Payment at the State Level

136. Medicaid providers are responsible for submitting claims for payment to the relevant state Medicaid program and are responsible for collecting applicable co-payments from the beneficiary. An NPI is required to be eligible to bill and receive reimbursement for medical services provided to TennCare enrollees. 42 C.F.R. § 455.440. Claims are primarily submitted electronically, but are sometimes submitted using a paper form.

137. In order to submit claims for payment to Government Healthcare Programs, providers must first become an approved provider for the particular Government program. This is accomplished, in part, by submitting a provider enrollment application and entering into a provider agreement placing the provider on notice, and obtaining the provider's assurance, that it will provide true, accurate, and complete claims data as a condition of participation in and receiving reimbursement from the program.

138. The paper claim form, CMS Form 1500, includes the following certification:

> NOTICE: This is to certify that the foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws.

139. The electronic claim form carries with it similar certifications that the information submitted is true, accurate, and complete.

140. As to the electronic claims, the Health Insurance Portability and Accountability Act ("HIPAA") requires pharmacies and state Medicaid programs to submit claims according to the National Council for Prescription Drugs Program Telecommunication Standard. *See* 42 U.S.C. §§ 1320d-1(a)(3) and 1320D-2(A)(2).

141. The term "medical assistance," defined at 42 U.S.C. § 1396d and Tenn. Code Ann. § 71-5-103(7), includes payment for the cost of provision of medical services or procedures by qualified, licensed practitioners to an eligible person.

142. TennCare will only pay for medical items and services that are within the scope of the TennCare program and that are medically necessary. Tenn. Code Ann. § 71-5-144(a).

143. In the present case, Defendants submitted claims for reimbursement to the State of Tennessee's Medicaid program, which in turn paid Defendants using a combination of state and federal funds. These claims were factually false and were otherwise fraudulent because they were for tests, services, and procedures that were not medically necessary, not reasonably necessary, and/or not otherwise payable.

b. Medicaid "Claims" for Payment at the Federal Level

144. Defendants' misconduct then caused the Medicaid program in Tennessee, which was unaware of the fraudulent nature of the claims for payment, to submit claims to the federal government for partial reimbursement pursuant to FMAP.

145. Through the FMAP process, state Medicaid administrators obtain the federal government's share of the provider's reimbursements by submitting a quarterly Form 64 to CMS. For this reason, claims for payment "presented" to state Medicaid agencies are also "presented" to the federal government within the meaning of the FCA.

146. The federal government also "approves" within the meaning of the FCA the claims submitted and paid through the Medicaid program. When a state presents its Form 64 (*i.e.,* the quarterly report of actual expenditures) to CMS, the amounts of any fraudulent claims the state paid will be included in those reports. Based on the information in the reports, CMS determines and approves whether the claims that the state paid with federal funds were appropriate.

147. If CMS determines certain claims paid by the state were improper, CMS may recoup the funds by reducing the amount of money provided to the state during the next quarter. In the present case, because Form 64 constitutes the United States' means for approving and paying the amount of federal funds expended by the state, these reports overstated the amount of federal funds to which the State was entitled by the amount fraudulently paid as a result of Defendants' scheme.

148. In short, Defendants' scheme caused to be made or used false records or statements material to false or fraudulent claims presented to the United States.

c. Medical Necessity / Reasonably Necessary

149. Medicaid's general coverage parameters, at both the federal and state levels, exclude items that are not "medically necessary" or provided economically (*i.e.*, "reasonable and necessary" from a fiscal perspective). 42 U.S.C. § 1320c-5(a)(1) (goods and services must be "provided economically and only when, and to the extent, medically necessary"); 42 C.F.R. § 1004.10(a) (same); Tenn. Code Ann. § 71-5-144(a), (b) (TennCare enrollees are eligible to receive, and TennCare shall provide payment for, only those medical items and services that TennCare determines to be medically necessary).

4. TRICARE

150. TRICARE is a medical benefits program established by federal law. 10 U.S.C. §§ 1071-1110b. TRICARE covers eligible beneficiaries, which include active duty members of the Uniformed Services and their dependents as well as retired members of the Uniformed Services and their dependents. The federal government reimburses a portion of the cost of health care services and prescription medications provided to TRICARE beneficiaries. TRICARE is administered by the Defense Health Agency.

151. TRICARE contracts with one of two contractors, including Humana Government Business, Inc., d/b/a/ Humana Military, to administer the TRICARE program, including the processing and payment of claims for reimbursement of physician and mid-level providers' services from TRICARE.

152. TRICARE covers only medically necessary inpatient and outpatient care. TRICARE defines medically necessary care as services or supplies provided by a hospital, physician, and/or other provider for the prevention, diagnosis, and treatment of an illness, when those services or supplies are determined to be consistent with the condition, illness, or injury; provided in accordance with approved and generally accepted medical or surgical practice; not primarily for the convenience of the patient, the physician, or other providers; and not exceeding (in duration or intensity) the level of care which is needed to provide safe, adequate, and appropriate diagnosis and treatments. *See* 32 C.F.R. § 199.4(a)(1)(i) and applicable definitions at

32 C.F.R. § 199.2. TRICARE regulations defining "medical necessity" also require that services and supplies be "furnished economically." 32 C.F.R. § 199.4(a)(1)(i).

153. TRICARE does not pay for services that are not authorized by law or that are fraudulently billed. 32 C.F.R. § 199.7(i)(3).

154. TRICARE regulations also provide that TRICARE may deny payment in "abuse situations." 32 C.F.R. § 199.9(b). To avoid abuse situations, providers are obligated to provide services and supplies under TRICARE that are: "Furnished at the appropriate level and only when and to the extent medically necessary . . .; of a quality that meets professionally recognized standards of health care; and, supported by adequate medical documentation as may reasonably be required under this part . . . to evidence the medical necessity and quality of services furnished, as well as the appropriateness of the level of care." *Id.*

155. TRICARE has specified examples of fraud or abuse against the TRICARE program as including "[m]isrepresentations of . . . description of services rendered." 32 C.F.R. § 199.9(c).

156. The TRICARE regulations, in turn, define "appropriate" medical care as that which is, *inter alia*, "[f]urnished economically"—i.e., "in the least expensive level of care or medical environment adequate to provide the required medical care." 32 C.F.R. § 199.2.

157. TRICARE requires maintenance of appropriate medical records to substantiate that billed services were actually rendered. 32 C.F.R. § 199.7(b)(3). Failure to document the care billed will result in denial of payment by TRICARE. *Id.*; TRICARE Policy Manual 6010.60-M, Ch. 1, § 5.1, ¶ 3.2.

158. TRICARE requires a prescription from the beneficiary's physician for laboratory tests.

159. Some TRICARE options require participating members to pay a co-pay and/or to meet a deductible. 32 C.F.R. § 199.4(f). A provider of services cannot, as a matter of law, waive these co-pay or deductible requirements. 32 C.F.R. § 199.4(f)(9).

160. As with Medicare, providers submit claims to TRICARE using the CMS 1500 or an electronic equivalent. Providers therefore make the same certifications in submitting claims to TRICARE as they do when submitting claims to Medicare.

161. Because it is not feasible for the TRICARE program, or its contractors, to review medical records corresponding to each of the claims for payment it receives from providers, the program relies on providers to comply with TRICARE requirements and relies on providers to submit truthful and accurate certifications and claims.

5. VA Health Benefits Programs

162. The United States offers medical benefits to qualified veterans through the Veterans Administration ("VA"). *See* 38 U.S.C. § 1701; 38 C.F.R. § 17.38(a). VA health benefits cover medical services only if "it is determined by appropriate healthcare professionals that the care is needed to promote, preserve, or restore the health of the individual and is in accord with generally accepted standards of medical practice." *Id.* § 17.38(b).

163. Pursuant to 38 U.S.C. §§ 1701 *et seq.*, the VA, through the Veterans Health Administration, provides and pays for inpatient and outpatient health care services for veterans and their dependents and survivors.

164. Beginning in August 2014, Congress enacted the Veterans Access, Choice, and Accountability Act of 2014 to enable eligible veterans to obtain medical care outside of the VA medical system from providers in their communities. Through this statute, veterans may enroll in the Veterans Choice Program ("Choice"), which provides primary care, inpatient and outpatient specialty care, and mental health care for eligible veterans when the local VA health care facility cannot provide the services for certain specified reasons, such as lack of available specialists, long wait times, or extraordinary distance from the veteran's home.

165. Congress also required the VA to develop a plan to consolidate all non-VA community care programs under Choice. The plan was required to address a number of elements, including "the structuring of the billing and reimbursement process, including the use of third-party medical claims adjudicators or technology that supports automatic adjudication." Choice

claims are processed on behalf of VA by third-party administrators ("TPAs"), which include TriWest Healthcare Alliance ("TriWest"). The services provided by the TPAs are governed by contracts between each TPA and the VA (the "TPA contracts") and include building provider networks, scheduling appointments, collecting medical documentation, and making payments for medical care.

166. Verification of eligibility in the form of an authorization from the TPA is required for reimbursement of costs associated with care provided to a veteran.

167. Once the provider is enrolled or credentialed, the provider may submit bills to the Government Healthcare Programs for services rendered to the patients. The TPA contracts require the providers of medical treatment to send their invoices to the TPAs, which must pay the providers and then bill the VA for these medical services.

168. VA and Choice only pay for covered services and supplies that are "medically determined to be reasonable and necessary." 38 C.F.R. § 17.30(a)(1).

6. The Federal Employee Health Care Programs

169. The United States Office of Personnel Management ("OPM") enters into contracts with qualified carriers to offer federal employees a variety of health insurance plans. *See* 5 U.S.C. § 8902.[2]

170. Separate funds are established to cover current employees, their families, and survivors (5 U.S.C. § 8909) and to cover postal service retirees, their families, and survivors (5 U.S.C. § 8909a).

171. To guard the federal fisc against fraud, waste, and abuse, Congress explicitly authorizes the OPM, acting through the Attorney General, to bring a civil action to recover a civil monetary penalty of not more $10,000 and an assessment of not more than twice the amount claimed from a health care provider who "knowingly made, or caused to be made, any false

[2] *See also* FEHB Program Handbook, OPM.gov (June 16, 2014) (available at http://www.opm.gov/healthcare-insurance/healthcare/reference-materials/fehb-handbook/) (last accessed April XX, 2020).

statement or misrepresentation of a material fact which is reflected in a claim presented under this chapter." 5 U.S.C. §§ 8902a(d)(2) and 8902a(i).

E. Regulations Regarding Coverage for Laboratory Tests

172. Laboratories have a "'legal duty to ensure that [they are] not submitting false or incorrect claims to Government . . . payors.'" *United States ex rel. Groat v. Boston Heart Diagnostics Corp.*, 296 F. Supp. 3d 155, 165 (D.D.C. 2017) (quoting Publication of OIG Compliance Program Guidance for Clinical Laboratories, 63 Fed. Reg. 45,076, 45,077 (Aug. 24, 1998)). As part of that duty, "laboratories should ensure that they do not submit claims for medically unnecessary tests by, *inter alia*, communicating with physicians regarding medical necessity, maintaining documentation of medical necessity, constructing requisition forms to promote conscious ordering of tests by physicians, and reviewing coding." *Id.* (citing 63 Fed. Reg. at 45,079-80). Courts have held laboratories liable under the FCA where they engage in schemes "to encourage . . . physicians to order medically unnecessary tests." *United States ex rel. Lutz v. Lab. Corp. of Am. Holdings*, No. 9:14-CV-3699-RMG, 2019 WL 236799, at *3 (D.S.C. Jan. 16, 2019) (quoting *Groat*, 296 F. Supp. 3d at 165).

173. Medicare and Tennessee Medicaid regulations both make clear that (a) laboratory tests must be ordered by the physician treating the patient for the treatment of a specific illness or injury; (b) laboratory test orders that are not individualized to patient need (or for which the need is not documented in the patient chart) are not covered services; and (c) claims for such services must be denied.

1. Medicare Coverage for Laboratory Tests

174. Laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), 42 U.S.C. § 263a, as set forth at 42 C.F.R. Part 493.

175. Medicare Part B pays for covered diagnostic laboratory tests that are furnished by a laboratory. 42 C.F.R. § 410.32(d)(v). "Clinical laboratory services involve the . . . examination of materials derived from the human body for the diagnosis, prevention, or treatment of a disease

or assessment of a medical condition." Medicare Benefit Policy Manual ("MBPM"), (Pub. 100-02), Ch. 15, § 80.1.[3]

176. Medicare Part B only covers services, including diagnostic laboratory services, that are reasonable and necessary for the diagnosis or treatment of an illness. *See* 42 U.S.C. § 1395y(a)(1)(A) ("[N]o payment may be made under [Medicare] part A or part B . . . for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]"); 42 C.F.R. § 411.15(k)(1).

177. Medicare regulations make clear that (a) laboratory tests must be ordered by the physician treating the patient for the treatment of a specific illness or injury; (b) laboratory test orders that are not individualized to patient need (or for which the need is not documented in the patient chart) are not covered services; and (c) claims for such laboratory services that do not meet these requirements are ineligible for payment and must be denied. Medicare Part B pays for covered diagnostic laboratory tests that are furnished by a laboratory. *See* 42 C.F.R. § 410.32.

178. The Secretary is responsible for specifying services covered under the "reasonable and necessary" standard and has wide discretion in selecting the means for doing so. *See* 42 U.S.C. § 1395ff(a).

179. The Secretary provides guidance to eligible providers pursuant to a series of Manuals, published by CMS, which are available to the public on the Internet. *See generally*, CMS Internet-Only Manuals (IOMs) (hereinafter "CMS Manuals").[4]

180. At all times relevant to this complaint, CMS contracted with MACs to act as agents in reviewing and paying claims submitted by health care providers. 42 U.S.C. §§ 1395h, 1395u; 42 C.F.R. §§ 421.3, 421.100, 421.104. MACs generally act on behalf of CMS to process and pay Part B claims and perform administrative functions on a regional level.

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[3] *See* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf (last accessed April XX, 2020).

[4] *See* https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms.html (last visited February 5, 2020).

181. As stated above, during the relevant time period of this Complaint, Cahaba and Palmetto were the MACs responsible for processing Medicare Part B claims in Tennessee.

182. As stated above, Medicare regulations require providers and suppliers to certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations. 42 C.F.R. § 424.516(a)(1).

183. Pursuant to 42 C.F.R. § 410.32(a), all diagnostic tests "must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." The Medicare Benefit Policy Manual's ("MBPM") "Requirements for Ordering and Following Orders for Diagnostic Tests" define an "order" as "a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary . . . [T]he physician must clearly document, in the medical record his or her intent that the test be performed." MBPM, Ch. 15, Section 80.6.1.

184. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary. 42 C.F.R. § 410.32(a). Clinical laboratory services must be ordered and used promptly by the physician who is treating the beneficiary as described in 42 C.F.R. § 410.32(a). MBPM, Ch. 15, § 80.1.

185. In order to assess whether those services are reasonable and necessary and whether reimbursement is appropriate, Medicare requires proper and complete documentation of the services rendered to beneficiaries. In particular, the Medicare statute provides that:

> No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

42 U.S.C. § 1395l(e); see also 42 U.S.C. § 1395u(c)(2)(B)(i) ("The term 'clean claim' means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) . . . .").

186. Medicare regulations expressly state that a laboratory's claim for a service will be denied if there is not sufficient documentation in the patient's medical record to establish that the service was reasonable and necessary. 42 C.F.R. § 410.32(d)(3).

187. CMS regulations further empower laboratories to request documentation from physicians regarding medical necessity:

> ***(iii) Medical necessity***. The entity submitting the claim may request additional diagnostic and other medical information from the ordering physician or nonphysician practitioner to document that the services it bills are reasonable and necessary.

42 C.F.R. § 410.32(d)(3).

188. The Medicare National Coverage Determinations Coding Policy Manual and Change Report currently states that "[s]ervices that are excluded from coverage include routine physical examinations and other services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury. CMS interprets these provisions to prohibit coverage of 'screening' services, *including laboratory test services furnished in the absence of signs, symptoms, or personal history of disease or injury*, except as explicitly authorized by statute." CMS, The Medicare National Coverage Determinations Coding Policy Manual and Change Report, 2 (Oct. 2015) (emphasis added).[5]

189. The HHS Office of Inspector General ("HHS-OIG") has published Compliance Program Guidance for Clinical Laboratories in the Federal Register. 63 Fed Reg. 45076 (Aug. 24, 1998).[6] Among other things, the HHS-OIG guidance clarifies that laboratory order forms should emphasize the need for a justification and assessment of each test ordered and that Medicare does not pay for tests for screening purposes:

> Therefore, Medicare may deny payment for a test that the physician believes is appropriate, but which does not meet the Medicare coverage criteria (e.g., done for screening purposes) or where documentation in the entire patient record, including

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[5] *See* https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/Downloads/manual201510_ICD10.pdf (last visited February 5, 2020).

[6] *See* https://oig.hhs.gov/authorities/docs/cpglab.pdf (last accessed April XX, 2020).

> that maintained in the physician's records, does not support that the tests were reasonable and necessary for a given patient. . . .
>
> a. Requisition design: While HCFA [(CMS)] does not design or approve requisition forms, laboratories should construct the requisition form to capture the correct program information as required by Federal or private health care programs and to promote the conscious ordering of tests by physicians or other authorized individuals. The laboratory should construct the requisition form to ensure that the physician or other authorized individual has made an independent medical necessity decision with regard to each test the laboratory will bill. . . . **The form should contain a statement indicating that Medicare generally does not cover routine screening tests**. . . .
>
> 4. Reliance on Standing Orders Although standing orders are not prohibited in connection with an extended course of treatment, too often they have led to abusive practices. **Standing orders in and of themselves are not usually acceptable documentation that tests are reasonable and necessary**. . . . Medicare contractors can and may require additional documentation to support the medical necessity of the test. **As a result of the potential problems standing orders may cause, the use of standing orders is discouraged**.

Id. at 45079, 45081 (emphasis added).

190. The OIG Compliance Guidance states that "laboratories should encourage physicians or other authorized individuals to submit diagnosis information for all tests ordered, as documentation of the medical necessity of the service" and that "Medicare generally does not cover routine screening tests." *Id.*

191. Significantly, OIG's Guidance explains that medical necessity will not be met generally for "routine screening tests," only tests that are "covered, reasonable, and necessary for the beneficiary, given his or her clinical condition." *Id.*

192. As a condition of Medicare payment, a physician or another Medicare-qualified clinician (such as physician assistants and nurse practitioners) must certify that the testing performed is medically necessary and reasonable for the diagnosis and treatment of the patient. 42 U.S.C. § 1395n(a)(2)(B); 42 C.F.R. § 424.10(a).

193. In some instances, recertification of the necessity of the services is also required by the physician. 42 C.F.R. § 424.10(a). The physician, nurse practitioner, clinical nurse specialist, or physician signing the certification must have knowledge of the case. 42 C.F.R. § 424.24(g)(2).

194. A claim is properly denied where the service provided is not reasonable and necessary and the necessity is not documented in the medical record, or if the MAC has made a local coverage determination that the service is not covered. 42 C.F.R. § 410.32(d)(2)(i)-(iii); (d)(3)(ii)-(iii).

2. Tennessee Medicaid Coverage for Laboratory and Other Tests

195. Tennessee Medicaid also requires that testing be medically necessary, reasonable, and individualized to the medical needs of patients:

> To be determined to be medically necessary, a medical item or service must be recommended by a physician who is treating the enrollee or other licensed healthcare provider practicing within the scope of the physician's license who is treating the enrollee and must satisfy each of the following criteria:
>
> (1) It must be required in order to diagnose or treat an enrollee's medical condition. The convenience of an enrollee, the enrollee's family, or a provider, shall not be a factor or justification in determining that a medical item or service is medically necessary;
>
> (2) It must be safe and effective. To qualify as safe and effective, the type and level of medical item or service must be consistent with the symptoms or diagnosis and treatment of the particular medical condition, and the reasonably anticipated medical benefits of the item or service must outweigh the reasonably anticipated medical risks based on the enrollee's condition and scientifically supported evidence; [and]
>
> (3) It must be the least costly alternative course of diagnosis or treatment that is adequate for the medical condition of the enrollee. . . . Where there are less costly alternative courses of diagnosis or treatment, including less costly alternative settings, that are adequate for the medical condition of the enrollee, more costly alternative courses of diagnosis or treatment are not medically necessary.

Tenn. Code Ann. § 71-5-144.

3. TRICARE Coverage for Laboratory and Other Tests

196. TRICARE only pays for laboratory tests that are "medically or psychologically necessary" and "required in the diagnosis and treatment of illness or injury." 32 C.F.R. § 199.4(a)(1). TRICARE will not cover tests that are "not related to a specific illness or injury or a definitive set of symptoms." *Id.* at (g)(2).

197. As noted above, TRICARE may deny payment in "abuse situations." 32 C.F.R. 199.9(b). Examples of abuse included in the regulations include: (i) "a battery of diagnostic tests are given when, based on the diagnosis, fewer tests were needed," and (ii) "[f]ailure to maintain adequate medical or financial records." *Id.*

4. Urine Drug Testing

198. Although testing urine for drugs may be an appropriate means to analyze and monitor the treatment of pain patients, as set forth below, the Clinic Defendants and the Lab Defendants used this tool as a means to bilk the United States and Tennessee out of millions of dollars.

a. General Guidelines on Urine Drug Testing

199. Typically, providers utilize drug tests to verify whether pain patients are compliant with taking their prescription drugs and to confirm that the patient is not taking other drugs, including illicit ones, which could interfere with their treatment or pose risks of overdose. For this reason, providers often perform drug tests on pain patients at appropriate intervals when medically necessary to manage the patient's care. When urine testing is medically necessary, the Government Healthcare Programs will provide reimbursement for such tests.

200. Common practice in the medical community is to first order a qualitative test of urine to detect the presence or absence of drugs or metabolites (often known as "analytes") in the sample. A typical qualitative drug test panel may include testing for the presence of cocaine, opiates, opioids, heroin, amphetamines, methamphetamine, benzodiazepines, phencyclidine ("PCP"), MDMA, barbiturates, methadone, tricyclic antidepressants, synthetic or designer drugs, oxycodone, and THC. Qualitative testing does not measure the concentration of drugs in the sample.

201. For patients deemed at high risk for the potential to abuse drugs, or if the provider has a concern about the drugs already in the patient's system, the medical community recommends on site Point-of-Care ("POC") testing to obtain immediate results of the qualitative testing. POC testing is reimbursed at a lower rate than testing performed off-site.

202. Depending on the initial results from the qualitative testing, it may, in some instances, be medically appropriate to next perform a quantitative drug test to determine the concentration of specific drugs in a patient's system. The purpose of quantitative testing is to confirm any positive results from the qualitative test and to determine the concentration of the specific drug(s) present. Unlike the qualitative test, which can test for all drugs in the sample at once, quantitative testing requires that a separate test be performed for each different drug. Because a separate test is required for each drug, the testing equipment needed is much more sophisticated than what is needed at the qualitative level. Thus, quantitative testing is more expensive to perform and is reimbursed at a higher rate than qualitative testing.

203. Medicare rules limit quantitative testing, in most cases, to clinical situations where qualitative testing has been performed and the results of that test indicate that quantitative tests for particular drugs are needed.

204. The frequency of qualitative drug testing also must be individualized to patient need in order to be reasonable and medically necessary. Ongoing testing in chronic opioid therapy patients can be acceptable, as can randomized testing, but only under specific conditions particular to the individual patient.

205. For this reason, the Government Healthcare Programs generally require providers to make testing decisions on a case-by-case basis, as most patients will not test positive for any drugs on a screening test (save those being prescribed to them), or if there are positive results, those are typically limited to no more than a few drugs.

206. Many of the MACs also require providers to assess patient risk on an individualized basis to determine the appropriate frequency of testing, as well as which urine drug tests should be performed.

207. For these reasons, most patients do not warrant quantitative urine drug testing. Even in those cases where quantitative testing is appropriate, it is rarely medically necessary to perform such testing for each of the drugs that the qualitative test detects.

208. On or about October 1, 2015, Cahaba issued a local coverage determination ("LCD"), L34501, entitled "Pathology and Laboratory: Qualitative Drug Testing." LCD 34501 stated qualitative testing "may be followed by confirmation with a second method, only if there is a positive or negative finding inconsistent with the setting of a symptomatic patient." In other words, the results must be received and analyzed prior to the provider ordering the quantitative testing. Cahaba further indicated: "Routine 'per visit' drug testing in chronic pain patients is noncovered." Thus, providers may not use a standing order that authorizes the same set of tests for each patient.

209. As of June 15, 2015, Cahaba provided notice to providers that effective October 1, 2015, LCD L35920, entitled "Pathology and Laboratory: Quantitative Drug Testing," would go into effect. This LCD expressly stated:

> physician-directed definitive profile testing is reasonable and necessary when ordered for a particular patient based upon historical use and community trends. However, the same physician-defined profile is not reasonable and necessary for every patient in a physician's practice. Definitive UDT orders should be individualized based on clinical history and risk assessment, and must be documented in the medical record. Some labs offer comprehensive definitive drug testing panel ("CDDP") of 40 or more drugs. It is not reasonable and necessary to bill individual billing codes for this comprehensive testing.

210. Cahaba further indicated: "Routine standing orders for all patients in a physician's practice are not reasonable and necessary. Physician-defined standing orders for pre-determined drug panels according to specific patient profiles for a limited sequential period may be reasonable and necessary and must be documented in the patient's medical record."

211. Palmetto's LCD 35724, which was effective October 1, 2015, did not allow for any standing orders with respect to urine drug testing, and instead required providers to engage in a patient-specific risk analysis to determine how often urine drug testing should be performed on patients. For low risk patients, random testing should occur "1-2 times every 12 months for prescription medications, non-prescribed medication that may pose a safety risk if taken with prescribed medications, and illicit substances, based on patient history, clinical presentation,

and/or community usage." For moderate risk patients, random testing should occur one to two times every six months. For high risk patients, random testing should be performed one to three times every three months. Palmetto also did not reimburse for specimen "validity testing including, but not limited to, pH, specific gravity, oxidants, creatinine."

212. The prior relevant LCD for Palmetto, LCD 35105, which was effective December 15, 2014, contained similar language.

213. From 2011 to 2015, qualitative testing was billed under codes G0431 and G0434.

214. In 2016, codes G0431 and G0434 were discontinued and replaced with G0477, G0478, and G0479 for presumptive testing. In 2017, these codes were replaced with CPT codes 80305, 80306 and 80307.

215. CDDP Panels and quantitative testing generally were billed under CPT code 84311 throughout the relevant time period.

216. Beginning in 2015, CPT code 80299 was used for quantitative testing for therapeutic drugs without a specific CPT code assigned. In 2016, CMS implemented HCPCS codes G0480, G0481, G0482 and G0483 for definitive or quantitative drug testing.

b. Reimbursements for Laboratory Tests

217. Different types of urine drug tests have different costs.

218. During the relevant time period, Medicare generally reimbursed presumptive UDT based on the methodology (analyzer versus POC test cup or strip) used by the physician practice or the complexity of the test under CLIA. During the relevant time period, POC tests were reimbursed by Medicare at a rate of $12-25 and high-complexity analyzer tests were reimbursed by Medicare at a rate of $65-$100.

219. Beginning January 1, 2017, presumptive UDT may be reported with CPT codes 80305-80307. These codes differ based on the level of complexity of the testing methodology. Only one code from this code range may be reported per date of service.

220. The descriptors for presumptive UDT codes are:

a. **80305**: Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) capable of being read by direct optical observation only (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service.

b. **80306**: Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) read by instrument-assisted direct optical observation (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service.

c. **80307**: Drug tests(s), presumptive, any number of drug classes, qualitative, any number of devices or procedures; by instrument chemistry analyzers (*e.g.*, utilizing immunoassay [e.g., EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (*e.g.*, GC, HPLC), and mass spectrometry either with or without chromatography, (*e.g.*, DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service.

221. Prior to January 1, 2016, definitive UDT was generally billed using individual CPT codes for each and every drug or drug class tested. In response to concerns regarding the potential for overpayment when billing for each individual drug test, CMS revised the way that it reimbursed definitive UDT under the Medicare program, effective January 1, 2016. *See* Calendar Year (CY) 2016 Clinical Laboratory Fee Schedule (CLFS) Final Determinations.[7] In particular, rather than continuing to permit providers to bill for each and every individual definitive drug test, CMS created four CPT codes for definitive UDT: G0480, G0481, G0482, and G0483. These codes differ based on the number of drug classes including metabolites tested. Only one of these four definitive UDT codes may be billed per patient per day. *Id.* The following table defines these codes and their corresponding 2016 Medicare reimbursement amount:

[7] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/Archive-Test-Codes-and-Payment-Determinations-files-.zip (last viewed February 5, 2020).

Definitive UDT Code	Definition	2016 Medicare Reimbursement
G0480	Definitive drug testing for 1-7 drug classes, including metabolites	$79.94
G0481	Definitive drug testing for 8-14 drug classes, including metabolites	$122.99
G0482	Definitive drug testing for 15-21 drug classes, including metabolites	$166.03
G0483	Definitive drug testing for 22 or more drug classes, including metabolites	$215.23

See id.; 2016 Clinical Diagnostic Laboratory Fee Schedule.[8]

222. During the relevant time period, TRICARE followed Medicare's reimbursement methodology for UDT.

223. Current coding for testing for drugs of abuse relies on a structure of "screening" (known as "presumptive" testing) and "quantitative" or "definitive" testing that identifies the specific drug and quantity in the patient.[9]

224. In addition, definitive drug testing code G0659 was created to recognize those laboratories that are performing a less sophisticated version of these tests than is usually performed in drug testing laboratories:

225. **G0659**: Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase), performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or

[8] *See* https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/16CLAB.zip (last visited February 5, 2020).

[9] *See* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMatters Articles/Downloads/SE18001.pdf (last accessed April XX, 2020).

other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes

226. The work performed in this test approximates the work performed in CPT code 80307.

VI. DEFENDANTS' MISCONDUCT

A. How Defendants Operated the Scheme

227. Defendants Michael and Debbie Cox own and operate two pain clinics. The primary clinic operates under the name Clarksville Pain Institute, and is physically located at 1849 Madison Street, Suite F, Clarksville, TN 37043. A Google Maps photograph of this location is pasted below:

228. As evident from the above photograph, the Clarksville Pain Institute is located in Suite F, at the far right of a small strip mall with six storefronts. Also at this location, but not marked with any visible signage, and accessed two doors down (i.e., Suite D), is the "in-house" pharmacy that filled the opioid and pain cream prescriptions for patients of the Cox's two pain clinics. Finally, located within the pharmacy storefront, but at the back of the space, is the "in-house" lab that processed the urine samples for patients of the Cox's two pain clinics.

229. The second clinic operates under the name Pain Institute of Springfield White House, and is physically located at 502 Northcrest Drive, Springfield, TN 37172.

230. As detailed in the next section, the present d/b/a names of the two clinics are assumed names of both Defendant CPI and Defendant PIN. Based on records on file at the

Tennessee Secretary of State, it appears that, effective January 1, 2019, the operations of both clinics moved from being under the umbrella of CPI to that of PIN.

231. While precise relationships between the named legal persons and the lab and pharmacy operations seem obscured, how the scheme worked is well known based upon Relator's experience working in a wide range of roles at the primary clinic on Madison Street. An overview of how the scheme worked is set forth below.

232. First, patients at the two pain clinics were typically referrals from other physicians. The primary treatment mode at both clinics was to prescribe patients some form of narcotic (*i.e.*, opioid) medication, which included Fentanyl patches, oxycodone, and morphine. Sometimes Dr. Stanton (who was only at the Clarksville clinic on Mondays, and was only at the Springfield clinic two Tuesdays per month) wrote these opioid prescriptions, but most often a nurse practitioner or a physician's assistant employed by the pain clinics wrote them.

233. Relator was told that nurse practitioners and physicians assistants are permitted to write prescriptions for opioids if a licensed physician is present during 20% of the operating hours of the clinic. *See* Tenn. Code Ann. § 63-1-309(c) ("A medical director shall be onsite at least twenty percent (20%) of the clinic's weekly total number of operating hours" and "shall serve as medical director and provide services for no more than four (4) pain management clinics."). Relator was also told that Dr. Stanton fulfilled this role.

234. Relator observed that most of the patients' charts included an electronically applied certification for signature by a physician attesting that that the physician had reviewed the patient's chart, and about 20% of them also stated that the physician had been present in the clinic during the visit. Dr. Stanton personally applied his electronic signature to some of these certifications. Relator observed, however, that some of the certifications attesting that he had been in the clinic during the patient's visit were obviously false, since the visit did not occur on a Monday—the only day Dr. Stanton was at the Clarksville pain clinic.

235. The opioid prescriptions were generally written for a 10-, 20-, or 30-day supply and required patients to return to the clinic frequently to get their prescriptions refilled.

236. Whether a new or refill prescription, the patients at the Clarksville location were instructed to take their prescription next door to the in-house pharmacy to have it filled. Relator heard Michael and Debbie Cox, and other employees at CPI, refer to the in-house pharmacy as the Cox Family Pharmacy, which was owned by CPI and/or PIN (in turn owned by Michael and Debbie Cox), and operated by John C. Prichard as the Director.

237. In other words, the Cox Defendants instructed their staff at the Clarksville pain clinic to self-refer the opioid prescription dispensing to a pharmacy they owned.

238. Defendant Debbie Cox admitted her ownership interest in the pharmacy in a Word document incident description she created, modified, and printed in November 2014. The incident description pertains to the termination of a pharmacy employee and states that the employee "was told upon hiring that any problems with the pharmacy to talk directly to the owner Debbie Cox."

239. "On or after July 1, 2017, no owner of a pain management clinic shall locate or participate in locating a pharmacy, as defined in [Tenn. Code Ann.] § 63-10-204, in which any owner has an ownership interest, in a location that is adjacent to the location of the clinic. Locating a pharmacy in which any owner of a pain management clinic has an ownership interest adjacent to the clinic shall result in the revocation of the license to operate the pain management clinic." Tenn. Code Ann. § 63-1-316(h). "Adjacent" is defined as "within 1,000 feet." Tenn. Comp. R. & Regs. 1200-34-01-.01(2).

240. Thus, as of July 1, 2017, the arrangements described above violated Tennessee law, were grounds for mandatory revocation of CPI's operating license, and rendered CPI ineligible to receive payments from Government Healthcare Programs from that date forward.

241. This intertwined ownership caused prescriptions to be based on profit rather than patient need. According to one nurse practitioner, she and other nurse practitioners were heavily pressured to write certain dosages more frequently than others because "Oxy 10mg brings in less profit than Oxy 15mg." Similarly, according to notes of an office meeting on September 18, 2013, Debbie Cox gave instructions with regard to charting that "if someone is calling saying they are selling pills should be noted and labled [sic] hearsay, unless it is a pharmaist [sic] that knows for

sure" and "Do not prescribe migrane [sic] medicine." These examples of management telling providers what to prescribe—or not to prescribe—confirms that CPI was instructing its providers to write prescriptions based on profit and financial interests in the pharmacy profit rather than on patient need or provider recommendations.

242. Relator's investigation revealed that Mr. Prichard not only serves as the Director of the Cox Family Pharmacy, but also owns Pharmacy Solutions, LLC (d/b/a Cox Pharmacy and Medsource Scripts), which is registered at the same location. This suggests that some of the prescriptions may have been billed through Pharmacy Solutions, LLC, as a vehicle for further compensating Mr. Prichard for his complicity in the scheme.

243. Either way, Defendant Prichard was the central figure at the in-house pharmacy. Relator frequently saw Defendant Prichard at the pharmacy and was told that he was the pharmacy director.

244. Prescribing addictive opioids for long-term use, however, was merely the hub to which additional, and medically unnecessary, services were tied. Defendants Michael and Debbie Cox were frequently at both clinics, where they also enforced strict standing orders for unnecessary additional services for patients. These medically unnecessary services can be broken down into two groups—testing and adjunct therapies.

245. The medically unnecessary testing services included: a) comprehensive allergy tests that were billed in an unbundled manner so as to maximize reimbursement from Government Healthcare Programs; b) psychological tests; and c) ongoing urinary tests. Each of these is described in greater detail in later sections of the Complaint. For purposes of this overview, however, the urinary tests bear further explanation, since they also implicate the in-house lab.

246. The ongoing urinary tests were processed at an in-house lab located at the back of the storefront housing the pharmacy. The lab was comprised of one large machine that analyzed the urine samples from both pain clinics. The lab was staffed by two part-time workers who alternated shifts. An employee of the Springfield location brought over urine samples daily from that clinic. As detailed in the next section, both Defendant NPI and Defendant John L. Stanton,

MD, P.C. are registered as having labs at this location. If the billings were done by the former, then the lab work was a self-referral; whereas, if the billings were done by the latter, then the lab work was a form of kickback to Dr. Stanton. Either way, the set-up violated federal laws designed to prevent precisely this type of overutilization motivated by greed, rather than medical necessity.

247. "Adjunct therapies" was another set of medically unnecessary billings. Again, this was part of the protocol enforced by Michael and Debbie Cox. In short, patients were required to select, and follow through with, two adjunct therapies provided in-house. These included steroid injections, back braces, and opioid pain creams:

a. Steroid injections were only performed by Dr. Stanton, who received direct compensation for providing these services. Importantly, if a patient failed to show up for an injection, the patient's primary opioid prescription was reduced in strength or duration to incentivize adherence to the pain clinics' policy requiring adjunct therapies.

b. Dr. Stanton also prescribed back braces. These very expensive back braces were stored in a closet at the pain clinics, and a medical assistant employed by the pain clinic "fitted" them. Once the back brace was fitted, the signed consent form and any other related paperwork were placed in a special folder labeled with the name of Dr. Stanton, who would personally pick up the folder and directly bill Medicare Part B for the back braces. Regardless of ongoing need, and even when patients said they never used this adjunct therapy that was forced upon them, as soon as the patient's third-party healthcare provider would pay for another back brace, a new one was fitted to the patient, and the requisite paperwork was placed in Dr. Stanton's folder.

c. CPI maintained an Excel spreadsheet that was most recently modified by Debbie Cox on May 21, 2013, noting patients for whom a back brace was ordered in April 2013. The document lists for each patient the insurance claim status (paid, denied, etc.) and the amount paid by insurance. CPI maintained a second Excel spreadsheet

that Debbie Cox created on May 21, 2013, and modified most recently on October 30, 2018, listing by patient name and date of service more than 500 back braces given at CPI from December 7, 2012, through May 6, 2015. These documents demonstrate the significant volume of back braces prescribed, the majority of which were medically unnecessary, and the significant amounts CPI was paid for them.

d. The in-house pharmacy filled opioid creams in advance of a patient's appointment. Every morning the pharmacy would deliver next door to the Clarksville pain clinic dozens of jars of pain cream for the patients scheduled to be seen that day at both pain clinics. The pain creams were prepackaged into bags, to which was stapled a sheet detailing the patient and the compound. An employee from the Springfield pain clinic came each day to pick up the pain creams for the patients to be seen at that location. When patients arrived at the pain clinics, an employee of the clinic—not the pharmacy—would collect from the patients any applicable co-payment for the pain cream and would then give the patients their pain cream.

B. Ownership Details of Defendant Entities

248. Through a series of unlawful alliances, self-referrals, kickbacks, and quid pro quos, Defendants created relationships and promoted arrangements between various entities and individuals that generated and were characterized by widespread overutilization of urine drug testing, injections, psychological testing, allergy testing, and compounded medications at the expense of patients and Government Healthcare Programs. Defendants billed many of these procedures, though medically unnecessary and not properly payable, to third-party payors, including Government Healthcare Programs.

249. CPI has three active assumed names: (1) White House Pain Institute (registered May 22, 2014, renewed April 1, 2019, and expiring April 1, 2024); (2) Nashville Pain Institute (registered January 13, 2017, and expiring January 13, 2022); and (3) Cox Family Pharmacy (registered May 10, 2017, and expiring May 10, 2022). White House Pain Institute was moved/changed to Pain Institute of Springfield (502 Northcrest Drive, Springfield, TN 37172).

250. CPI's registration of the first assumed name, White House Pain Institute, was done at the same time that papers were filed merging White House Pain Institute, LLC (formed May 6, 2013) into CPI, although the merger's effective date was delayed a few days until May 30, 2014. According to the Tennessee Secretary of State, White House Pain Institute, LLC is listed as "Inactive-Merged," but still shows a principal address of 491 Sage Road North, White House, TN 37188-9363.

251. Upon information and belief, White House Pain Institute, LLC had a certified "physician office" clinical testing lab located at 491 Sage Road, Suite 1100, White House, TN 37188. This location is not presently listed as one of the two locations on Defendants' two mirrored websites.[10]

252. Upon information and belief, CPI's registration of the assumed name "Cox Family Pharmacy" on May 10, 2017, corresponds to the "Cox Pharmacy" that Mr. Cox opened in October 2014.[11] A reliable online source lists Cox Family Pharmacy as having NPI Number 1710395116, enumerated on July 29, 2014.[12]

253. The ownership and operation of the onsite pharmacy part of this scheme are complicated by another pharmacy, MedSource Scripts, registered for that same location.[13] According to a reliable online source, MedSource Scripts is assigned NPI Number 1295274306, enumerated on February 22, 2017.[14] That source also lists MedSource Scripts as a d/b/a/ of Pharmacy Solutions LLC, which is the Tennessee LLC that registered the assumed name "Medsource Scripts" on August 28, 2017.

254. Interestingly, on the same date, Pharmacy Solutions LLC also registered the assumed name "Cox Pharmacy." The Tennessee Secretary of State lists "John C. Prichard" as the contact person for Pharmacy Solutions LLC, and its principal place of business as 1849 Madison

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[10] *See* http://www.clarksvillepaininstitute.com (last accessed April XX, 2020); http://whitehousepaininstitute.com (last accessed April XX, 2020).
[11] http://clarksvillepaininstitute.com/pain-institute-providers/michael-cox/ (last accessed April XX, 2020).
[12] https://npidb.org/organizations/suppliers/community-retail-pharmacy_3336c0003x/1710395116.aspx (last accessed April XX, 2020).
[13] https://pharmacygps.com/drugstore/medsource-scripts-1295274306/ (last accessed April XX, 2020).
[14] https://npino.com/pharmacy/1295274306-medsource-scripts/ (last accessed April XX, 2020).

Street, Suite D, Clarksville, TN. Mr. Prichard holds a Pharm.D., Tennessee License Number 37280, and is assigned NPI Number 1235578030, enumerated on June 14, 2013.[15] Relator knows Dr. John Christian Prichard to be the person held out as the "Pharmacy Director" of Cox Pharmacy/MedSource Scripts, located at 1849 Madison Street, Suite D, Clarksville, TN.

255. In short, in October 2014, Mr. Cox opened a pharmacy at 1849 Madison Street. On May 10, 2017, CPI (whose principal contact is Mr. Cox) registered the assumed name "Cox Family Pharmacy" (NPI 1710395116). Just a few months later, on August 28, 2017, Pharmacy Solutions, LLC (whose principal contact is Mr. Prichard (NPI 1235578030)), the Pharmacy Director) registered the assumed name "Cox Pharmacy," while also operating at the same location MedSource Scripts (NPI 1295274306). Hence, there are intertwined ownership and business interests that suggest the Clinic Defendants and the Prescribing Defendants may be permitting the Pharmacy Defendants to bill some of the illicitly generated, and medically unnecessary, prescriptions through personal or corporate NPIs, and thereby profit from their complicity and silence.

256. As to how the pharmacy is used in Defendants' schemes, Relator personally observed that a pharmacy is operated at 1849 Madison Street, Clarksville, TN 37043. Relator also personally observed that CPI patients are often prescribed opioid pain medications (such as creams, pills, or patches), which prescriptions the on-site Cox Family Pharmacy then dispensed and billed. One of CPI's former nurse practitioners is known to be a high prescriber of opioids.

257. On December 13, 2018, PIN added two active assumed names: (1) Pain Institute of Clarksville (expires on December 13, 2023); and (2) Pain Institute of Springfield/Whitehouse (expires on December 13, 2023). These assumed names are currently listed as the two current d/b/a's, with separate locations, on two mirrored websites.[16]

258. On both websites, the clinic names and locations are stated as: (1) "Pain Institute of Clarksville," 1849 Madison St., Suite F, Clarksville, TN 37043, phone 931-802-6824; and (2)

[15] https://npino.com/pharmacist/1235578030-john-christian-prichard/ (last accessed April XX, 2020).
[16] *See* http://www.clarksvillepaininstitute.com (last accessed April XX, 2020); http://whitehousepaininstitute.com (last accessed April XX, 2020).

"Pain Institute of Springfield White House," 502 Northcrest Dr., Springfield, TN 37172, phone 615-581-0091. In short, it appears that as of January 2019, Debbie and Michael Cox shifted business operations from the umbrella of Clarksville Pain Institute, LLC to the umbrella of Pain Institute of Nashville PLC.

259. Pain Institute of Nashville PLC has a certified "physician office" clinical testing lab located at 1849 Madison Street, Suite F, Clarksville, TN—*e.g.*, at its sister clinic.

260. The improperly intertwined business and ownership interests do not stop there. As noted above, according to filings with the Tennessee Secretary of State, Dr. Stanton is the registered agent of John L. Stanton, MD P.C. (a professional corporation located at 980 Professional Park Drive, Suite A, Clarksville, Tennessee).

261. John L. Stanton, MD P.C. has a certified "physician office" clinical testing lab located at 1849 Madison Street, Suite D, Clarksville, TN 37043.

262. Except for a different suite number, this lab is at the same location as the CPI clinic, and the principal place of business listed with the Tennessee Secretary of State for both CPI and PIN.

263. Dr. Stanton's roles as Medical Director and/or Orthopedic Surgeon for CPI (including the Pain Institute of Springfield/White House location) and at the related/adjacent lab, Michael Cox's role at CPI and his ownership of the related/adjacent pharmacy, and Dr. Prichard's roles at Pharmacy Solutions LLC and as the "Pharmacy Director" of Cox Pharmacy/MedSource Scripts sparked and fueled self-referrals, kickbacks, and overutilization at issue in violation of the FCAs, the AKS, and Stark.

C. Relator Nicholson Held Positions from Which She Directly Observed Defendants' Misconduct

264. As stated above, Relator began working at CPI in August 2018. She came to the position with formal training and certification as an EMT, and she held several different positions while employed by CPI.

265. As Medical Assistant, Relator was responsible for patient intake (*i.e.*, vitals), maintaining and creating patient charts and visit summaries for nurse practitioners before patient visits, administering psychological testing, administering and billing for allergy testing, and fitting back braces.

266. As Injection/Fluoroscopy Technician, Relator's duties included patient intake (*i.e.*, vitals), ensuring consent forms were signed by every patient before every procedure, operating the fluoroscopy C-arm x-ray machine during procedures, documenting and charting for consultations and injection procedures, preparing supplies and injection medication, maintaining a stock of injection supplies and medication, and billing for injection procedures.

267. As Urine Drug Screen Technician, Relator's responsibilities included collecting urine samples from every patient (on every visit), preparing samples for lab analysis, and uploading completed urine drug test results. Relator was also responsible for creating lab requisitions, which, per a standing order, was the same 18-drug panel/quantitative test for each patient rather than an individualized, patient-specific order.

268. As Receptionist, Relator was responsible for patient intake and check-in; collecting copays, balances, and payments for pain cream; inputting insurance demographics and certifying insurance eligibility; collecting, handling, and maintaining balances of cash and card payments; answering phones; and coordinating patient and provider scheduling.

269. As Prior Authorization Coordinator, Relator was responsible for initiating and obtaining prior authorizations for medications and procedures prescribed and performed in the clinic, completing eligibility forms to get medications and procedures approved by insurance

companies, faxing patient charts, and liaising between CPI practitioners, patients, and insurance companies regarding patient approval/denial status.

270. From the vantage points of these varied positions, Relator observed or had access to information about the violations of the FCA, the TFCA, and the TMFCA alleged below.

D. False Claims for Urine Drug Testing

a. How Defendants Executed this Scheme

271. The Clinic Defendants and the Lab Defendants knowingly submitted and caused to be submitted false claims to Government Healthcare Programs for urine drug testing that was not reasonable and necessary. *See*, *e.g.*, 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 410.32(a); MBPM, Ch. 15, Section 80.6.1.

272. The Clinic Defendants and the Lab Defendants ordered excessive numbers of urine drug tests, in part through the promotion of "custom profiles," which, instead of being tailored to individual patients, were in effect standing orders that resulted in large numbers of tests without an individualized assessment of each patient's needs.

273. Urine drug tests were and are mandatory at CPI. Under the Clinic Defendants' and the Lab Defendants' instructions and policies, every patient must provide a urine sample at every visit (which was every 28 days for established patients, and every 14 days for new patients). CPI considered a patient "new" on the first visit and on the second visit (which was scheduled for 14 days after the first visit). CPI considered a patient "established" on the third visit (which was scheduled for 14 days after the second visit) and on all subsequent visits (which were scheduled to occur every 28 days).

274. Patients' medical charts often stated "(y)," indicating to the urine drug test technician that the patient would get a full panel drug test. Upon seeing the "(y)," the urine drug test technician would create a lab requisition/order under name of the nurse practitioner who was seeing the patient. All orders were for the same full panel as a standing order (same process and boxes clicked every patient, every time). As discussed below, the "(y)" also indicated to the medical assistant that the patient needed a psychological test. This "(y)" is the order for the

majority of patients; "(n)" was used only on patient charts who were either self-pay or in rare instances for unknown reasons on various other insurances.

275. CPI maintained a Google document entitled "The Pain Institute: Policy and procedures for tx." A former provider at CPI named Erin Gardiner created the document, which was given to new CPI practitioners for reference during their training and employment at CPI. The document was originally the policy and procedures published by the State of Tennessee. However, it was edited throughout, as evidenced by the "changes history" accessed within the Google document. One of those edits was to change "should" to MUST in verbiage regarding urine drug screens. This change demonstrates CPI's focus on requiring urine drug testing more than was necessary or appropriate.

276. CPI's lab director would come by every afternoon to pick up the urine specimens and take them next door to the lab to be screened. By the patient's next visit, a .pdf result of the test would be available. A urine drug test technician would then mark which substances were noted during the test and upload the .pdf as a document.

277. The Clinic Defendants' and the Lab Defendants' practitioners rarely, if ever, used these results to determine patient care. When a discrepancy was found (such as cocaine, meth, fentanyl, THC, etc.), a "warning" would be put in the charting. However, the patient would still be prescribed the same amount of medication as per the patient's prior drug regimen, without any adjudgment to account for the discrepancy.

278. At the end of a urine-drug-test-related visit, when CPI practitioners were finalizing their paperwork, they "billed" a procedure identified in the CPI billing system as "HC 18 Panel UDS." However, for actual billing purposes, this "HC 18 Panel UDS" was unbundled and broken up into 18 different CPT codes. At all relevant times, this was the standard procedure for all insurance patients, including beneficiaries of Government Healthcare Programs. Self-pay patients did not receive an 18-panel urine drug test, regardless of condition, history, risk, etc., because of the lack of profit.

279. Documentation obtained by Relator from Aprima, the billing software CPI used, establishes the lack of medical necessity related to urine drug tests the Clinic Defendants and the Lab Defendants billed.

280. Below are examples from Aprima of false billing for urine tests.

281. For a single date of service (December 29, 2014), CPI billed Medicare (and Medicare paid) $1,673 for urine drug tests and psychological testing administered to a single patient, whose name Relator does not know. According to the invoice for that patient, CPI billed and was paid for the following codes (some with more than one unit):

99213 Established Patient Office Visit
80154 Assay of Benzodiazepine
82542 Column chromatography/mass spectrometry
82646 Assay of Dihydrocodeinone
83925 Assay of Opiates
80102 Drug Confirmation
80171 Drug Screen Quant Gabapentin
82145 Assay of Amphetamines
82205 Assay of Barbiturates
82520 Assay of Cocaine
82649 Assay of Dihydromorphinone
83805 Assay of Meprobamate
83840 Assay of Methadone
83992 Assay of Phencyclidine (PCP)
83887 Assay of Nicotine and Metabolites
82570 Assay of Urine under Chemistry Procedures
83986 Assay of pH; body fluid, not otherwise specified
82055 Assay of Ethanol
84311 Spectrophotometry, quantitation of analyte
96102 Psychological testing per hour by a technician

282. This invoice shows what CPI typically billed for urine tests for each Medicare patient on each visit (which was required every 28 days for established patients) during the time period prior to January 1, 2016, when individual quantitative tests were billed.

283. For a single date of service (March 14, 2019) after the coding was changed, CPI billed TennCare $588 for urine drug tests administered to patient B.M.:

- 80307: Drug tests(s), presumptive, any number of drug classes, qualitative, any number of devices or procedures; by instrument chemistry analyzers (e.g., utilizing immunoassay

[e.g., EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (e.g., GC, HPLC), and mass spectrometry either with or without chromatography, (e.g., DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS

- G0483: Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 22 or more drug class(es), including metabolite(s) if performed

284. CPI billed Government Healthcare Programs on many occasions in this same way, using the highest-paying code in the G0480-G0483 series.

b. The Clinic/Lab Defendants "Knowingly" Submitted False UDT Claims

285. CPI maintained a file titled "udt-in-pain-mgmt-and-opioid-abuse-treatment-medical-policy-2016." This file is coverage criteria for urine drug testing published on June 11, 2015 (effective September 11, 2015) by BlueCross Blue Shield of Vermont entitled "Urine Drug Testing in Pain Management and Opioid Abuse Treatment Corporate Medical Policy." The policy contains several statements that support CPI's scienter, including, among other things, the following:

- "Quantitative/definitive or confirmatory testing is medically necessary only when there is a positive finding (e.g., presence of a substance not prescribed); OR a negative finding when a positive result is expected; OR there is no immunoassay test commercially available."

- "Quantitative/definitive or confirmatory testing should be ordered with an indication of the specific drug being confirmed (e.g., order the individual substance(s) at question instead of a comprehensive confirmatory panel)."

- "In outpatient pain management and outpatient substance abuse treatment, . . . routine qualitative/presumptive or quantitative/definitive urine drug testing (eg, testing at every visit, without consideration for specific patient risk factors or without consideration for whether quantitative testing is required for clinical decision making)" is "considered not medically necessary. . ."

- "Testing performed as described below is not eligible for reimbursement:

    - Routine qualitative/presumptive or quantitative/definitive or confirmatory urine drug testing (e.g., testing at every visit)
    - Unbundled tests when using a multi-test kit screening (e.g. strip, dip card, or cassette)
    - Quantitative/definitive or confirmatory testing instead of drug screening, or as a routine supplement to drug screens
    - Qualitative/presumptive, quantitative/definitive or confirmatory testing orders for 'custom profile' or 'conduct additional testing as needed'
    - Quantitative/definitive or confirmatory testing that is indiscriminately carried out without a positive or unexpected negative result
    - Quantitative/definitive or confirmatory testing of negative point-of –care results, and expected positive results (i.e., known prescribed drugs)"

286. CPI also had in its possession the 2016 Annual Physician Notice from Millennium Health, a specialty laboratory that performs nationwide medication monitoring and drug testing services. This document explained the importance of billing federal health care programs correctly; complying with applicable NCDs and LCDs; and documenting thoroughly and correctly. The document also listed the proper CPT codes for urine drug testing along with reimbursement rates. The document warned (with emphasis): "The Office of Inspector General takes the position that a physician who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties under the False Claims Act."

287. Insurance companies routinely audit entities like CPI. According to Stacy Broadbent and email correspondence between CPI's owner and the billing manager (who was in charge of doing "chart pulls" to give to insurance companies to make sure the charting matched what CPI was billing), CPI chose approximately five "model" charts and updated them yearly to avoid a more thorough audit. Thus, CPI kept five charts that would pass an audit, so no red flags would come up in the yearly audit.

288. CPI's bilking of Government Healthcare Programs through unnecessary urine tests and its knowledge that such extensive testing is not medically necessary are evident in its practice

of treating self-pay patients under different policies and practices than those applicable to beneficiaries of Government Healthcare Programs.

289. CPI only tests self-pay patients' urine in a POC (point of care) urine cup, which is then disposed of and never subjected to the more elaborate and expensive urine drug screen testing.

290. According to an internal memo, effective May 1, 2012, CPI charged self-pay patients only $198.00 (which includes a $22.00 urine drug screen) for a first office visit and only $121.00 (which also includes a $22.00 urine drug screen) for all subsequent visits.

291. According to a CPI invoice, on April 8, 2019, patient R.M. was seen in the office for low back pain. Because patient R.M. was self-pay, CPI charged only $200 for the visit, which would have cost approximately $800-$1700 for a Medicare patient.

292. In addition, patient R.M.'s invoice shows there was no charge for an 18-panel urine drug test. This is because CPI did not actually perform the 18-panel urine drug test. When self-pay patients provide urine samples, CPI read them only through the cheap POC cups before throwing them away. CPI sent a urine sample to the lab for a qualitative and/or quantitative drug test only if the patient had insurance.

293. CPI maintained an Excel spreadsheet titled "CPI UDS 2018-2015." This file lists by month, year, and payor the number of drug tests that CPI billed to various payors from June 2013 to March 2019. Of the 42,851 total urine drug tests procedures billed, 15,542 (or 36.2%) were billed to Medicare, 3,564 or (8.3%) were billed to TRICARE, and 2,438 (or 5.7%) were billed to TennCare. Thus, CPI knew that Government Healthcare Programs paid approximately one-half (50.2%) of all urine drug tests it billed during this time.

294. The Clinic Defendants and the Lab Defendants maintained a spreadsheet that lists by month, year, and payor the number of drug tests that White House Pain Institute billed to various payors from January 2014 to February 2019. Of the 18,835 total urine drug tests billed, 6,567 (or 34.9%) were billed to Medicare, and 813 (or 4.3%) were billed to TennCare. Thus, the Clinic Defendants and the Lab Defendants knew that Government Healthcare Programs paid more than one-third (39.2%) of all urine drug tests White House Pain Institute billed during this time.

295. Medicare only covers tests that are reasonable and necessary for the treatment or diagnosis of an individual patient's illness or injury, based on his or her medical condition. 42 U.S.C. § 1395y(a)(1)(A). The need for each test for each patient must be individually assessed and documented in the patient's medical chart. At CPI, however, the need for "each test" was never individually assessed or documented in any chart. *See* 42 C.F.R. §§ 410.32(a), (d)(2). Medicare was billed for each drug or drug class tested—averaging more than seventeen procedure codes (many with multiple units) per urine sample—including tests for drugs that patients were not suspected of taking (or for substances rarely seen in the patient population (PCP, heroin, meth, etc.), and for "confirmatory" quantitative tests of expected in-office screening test results.

E. False Claims for Injections

a. How Defendants Executed the Scheme

296. The Clinic Defendants and the Lab Defendants performed and billed Government Healthcare Programs for many injections that were not medically necessary and were not payable.

297. In many cases, the Clinic Defendants and the Lab Defendants falsified medical necessity for injections on prior authorizations to get third-party payors to approve them and falsified diagnoses to get third-party payors to pay for them. For example, Medicare requires the diagnosis "spondylosis" for medial branch block injections. The Clinic Defendants and the Lab Defendants added this diagnosis for many patients for the sole purpose of getting the injection approved and paid. In addition, because prior authorizations require at least 50% improvement to allow more injections, the Clinic Defendants and the Lab Defendants often falsified the effectiveness of the injections in order to get more injections approved.

298. One type of injection for which the Clinic Defendants and the Lab Defendants falsely billed Government Healthcare Programs was sacroiliac ("SI") joint injections. The SI joint is a diarthrodial, synovial joint that is formed by the articular surfaces of the sacrum and iliac bones. The SI joints bear the weight of the trunk and, as a result, are subject to the development of strain and/or pain.

299. If the cause of pain in the lower back has been determined to be the SI joint, one treatment option is injecting steroids and/or anesthetic agent(s) into the joint. Therapeutic injections of the SI joint should not be performed unless other noninvasive treatments have failed.

300. Image guidance is crucial to identify the optimal site for access to the joint. Fluoroscopy is often the imaging method of choice.[17] Once the specific anatomy is identified, the needle tip is placed in the caudal aspect of the joint and contrast material is injected. Contrast fills the joint to delineate integrity (or lack thereof) of articular cartilage, as well as morphologic features of the joint space and capsule.

301. The injection procedure of the SI joint is considered medically reasonable and necessary when it is used for imaging confirmation of intra-articular needle positioning for arthrography with or without therapeutic injection. In addition, the injection procedure of the SI joint is considered medically necessary when an injection is given for therapeutic indications, such as injection of an anesthetic and/or steroid, to block the joint for immediate and potentially lasting pain relief. When therapeutic injections of the SI joint are performed, it would be expected that the record reflects noninvasive treatments (*e.g.*, rest, physical therapy, nonsteroidal anti-inflammatory drugs, etc.) have failed.

302. CPT code 27096 describes the injection of contrast for radiologic evaluation associated with SI joint arthrography and/or therapeutic injection of an anesthetic/steroid. CPT code 27096 should be billed only when imaging confirmation of intra-articular needle positioning has been performed. Per LCD L31359, when billing for services rendered to Medicare patients, CPT "code 27096 is to be used only with imaging confirmation of intra-articular needle positioning."[18]

303. CPT code 20552 describes single or multiple trigger point injections into one or two muscles.

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[17] A fluoroscopic guided injection involves injecting medicine directly into a joint using a type of imaging known as a C-arm, which provides real-time images of bones.

[18] https://downloads.cms.gov/medicare-coverage-database/lcd_attachments/31359_1/L31359_MS009_CBG_010111.pdf (last accessed April __, 2020).

304. CPT code 20610 describes aspiration (removal of fluid) from, or injection into, a major joint (defined as a shoulder, hip, knee, or subacromial bursa), or both aspiration and injection of the same joint. The procedure may be performed for diagnostic analysis and/or to relieve pain and swelling in the joint.

305. CPI practitioners rendered many injection services for which CPT code 20610 was billed, including services billed to Government Healthcare Programs.

306. In mid-January 2019, Relator became the Injection/Fluoroscopy Technician. In that role, she assisted with fluoroscopic guided injections, which were scheduled on Mondays at CPI and the first two Tuesdays at the White House/Springfield location. She also billed those procedures.

307. Relator's duties as Injection/Fluoroscopy Technician included patient intake (vitals), ensuring consent forms were signed by every patient before every procedure, operating the fluoroscopy C-arm x-ray machine during procedures, procedure documentation, charting for consults and injection procedures, preparing supplies/injection medication, maintaining stock of injection supplies and medication, and billing for injection procedures.

308. According to Medicare claims data, from 2014 to 2017, CPI practitioners (Dr. John Stanton, Debbie Cox, and Dr. Jianping Sun), using CPT code 20610, billed Medicare Part B for more than 1,000 injections administered to more than 650 beneficiaries.

309. Many, if not most, of these injections and the other injections for which CPI practitioners billed Medicare were SI joint injections.

310. Many, if not most, of these billings to Medicare for CPT code 20610 were false claims and were not reimbursable by Medicare. This is because, as instructed in LCD L31359, "[i]t is not appropriate to use CPT code 20610, Arthrocentesis, aspiration and/or injection; major joint or bursa (eg, shoulder, hip, knee joint, subacromial bursa) for SI joint injections" administered to Medicare patients.[19]

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[19] *See* https://downloads.cms.gov/medicare-coverage-database/lcd_attachments/31359_1/L31359_MS009_CBG_010111.pdf (last accessed April __, 2020) (last accessed April XX, 2020).

b. The Billing Manager Pushed Back Against Relator's Concerns

311. In mid-January 2019, Megan Rabbitt, CPI's billing manager (who also worked for Medical Data Services, LLC, a private medical billing company), began sending Relator weekly emails, the day after she assisted with and billed injections, with accusations that she was billing SI joint injections incorrectly.

312. As discussed above, there was variance in the procedures (and CPT codes) depending, among other things, on whether fluoroscopy was used to guide the injection. Relator billed properly for SI joint injections that did not use fluoroscopy using CPT code 20552, which had a lower rate of pay. However, Rabbitt told Relator that she was billing SI joint injections incorrectly and should use CPT code 27096, which included fluoroscopy, and CPT code 20610.

313. Rabbitt was incorrect. CPT code 27096 was not appropriate because the SI joint injections did not use fluoroscopy, and CPT code 20610 was not appropriate because, per Medicare coverage criteria, this code was not to be used for SI joint injections.

314. Relator researched the CPT codes herself and concluded that she was billing correctly, according to Medicare guidelines, by using CPT code 20552.

315. Relator then talked with Rabbitt and respectfully defended her billing. She showed Rabbitt the codes and what was in the charts, as well as references from Medicare and other payors that showed that Relator's use of CPT code 20552 for SI joint injections was correct. Rabbitt said "no, just change it to 20610." Rabbitt further said, "Well, that's how we've always done it, so I don't know," which was a common answer to Relator's questions at CPI. Relator told Rabbit that she was going to keep following the Medicare guidelines because she did not want to get into trouble. At the end of the conversation, Relator observed Rabbitt sit at her computer and change Relator's correct billings of CPT code 20552 to code 20610, which generated a higher billing.

316. At some point, Rabbitt gave Relator an email from her "colleague" at MDS (Medical Data Services, LLC) stating that CPI's method of coding was correct. Relator did not believe the email was correct since it did not provide any justification for billing CPT codes 27096 or 20610 for SI joint injections.

317. Relator continued to use the correct CPT code (20552) when billing for injections. She did not receive any further objections from Rabbitt with respect to billing. This led Relator to conclude that CPI was changing Relator's coding after she entered the billing, thereby causing the submission of false and upcoded claims to government payors. CPI never provided Relator with reliable evidence that her conclusions about CPI's illegal billing practices were incorrect.

c. Defendants "Knowingly" Billed False or Fraudulent Claims for Injections

318. The Cox Defendants and the Clinic Defendants enforced a policy requiring patients to select two adjunct therapies, despite a lack of medical necessity. With respect to injections, they punished patients for failing to adhere to the therapy schedule and thereby generated revenue not only for the clinics, but for Dr. Stanton who personally administered injections. In other words, these Defendants first facilitated the patients' addiction to opioid pain medications, and then used that addiction to manipulate their compliance with medically unnecessary—and potentially dangerous—steroid injections.

319. For example, internal CPI meeting notes state: "Medicare pt. not doing their injections will be put on a 7 day plan for 3 weeks." This indicates that CPI changed treatment (and imposed punishment) based on the patient's insurance situation. Medicare paid more for the more expensive injections, which gave CPI reason to ensure patients were getting their injections. CPI did not give "self-pay/other ins" patients the same treatment or punishment for missing injections because they were not the big money targets.

320. CPI's policy in this regard was also embodied in patient registration forms that patients were required to fill out before their first appointment at CPI. One of those pages described CPI's "no show" policy, under which "if an injection is missed, the patient will receive a 10% reduction in medication. The injection appointment will then be scheduled for the next injection date." This common practice at CPI was both harsh and improper. The decision to decrease a patient's medication should be based on sound clinical judgment, not the simple fact the patient missed an appointment.

321. Similarly, CPI used a patient signature form stating that "missing an injection is a $50 no show fee and a reduction in your medicine." This is another example of forcing injections and punishing patients for not getting injections.

322. In another new patient packet that CPI sent to patients before their first appointment, to be filled out and brought in the day of first appointment, is a reference to CPI policies dating back to 2014. Regarding the no-show policy for missing injections, one of those pages states, in bold, that "if an injection is missed you will only receive a 7 day Rx…" This shows that CPI used the narcotic prescriptions to entice unnecessary (and sometimes notably ineffective) injections. If patients missed injections or did not schedule them for one of their two adjunct therapies, CPI would withhold their prescriptions.

323. In April 2019, while looking through charts in the electronic health record, Relator discovered a peculiar and disturbing trend. In 2017, some patient injections were charted under Michael Cox's name, but had a different patient's name and date of birth in the chief complaint area.

324. Relator possesses evidence that shows on one particular day, Dr. Stanton triple-booked with consults from 3:00 to 3:15 pm. One of those three consult patients was listed as Michael Cox, but instead of the insurance and type of procedure, a different patient's name, date of birth, and phone number were listed. This was repeated on subsequent visits.

325. Relator also possesses evidence of an archived schedule from August 2017 that lists Michael Cox as the patient and as having been "seen" by Dr. Stanton. This was repeated on multiple dates. However, under the chief complaint section, different patients' information is listed, indicating that these patients were the ones being injected—or least under whose name the billings were submitted, not Michael Cox, as the records falsely indicated.

326. Relator also possesses evidence showing a different date of service listing Michael Cox as having been seen for an injection that was possibly administered to a different patient listed in the chief complaint section of the record.

327. Relator also possesses evidence in the form of internal CPI meeting notes that describe a patient being treated/injected in the wrong area, which management subsequently justified falsely in the medical record.

328. Documents describe Dr. Stanton's limited presence at various clinics, casting doubt on whether he was sufficiently supervising clinic personnel. For example, a memo from Dr. Stanton dated January 4, 2019, states: "I'm at the Clarksville Pain Institute on every Monday. I'm at the White House Pain Institute on all Tuesdays except the first Tuesday each month. I'm at the Clarksville [P]ain Institute on that first Tuesday each month. On Wednesdays I'm at the Joint and Spine [P]ain Clinic and on Thursdays at Gateway Medical [A]ssociates clinic. I do go to the White House Pain Institute on random Fridays, usually 1 per month."

329. In addition, when Relator was trained for checkout, she was given a handwritten training packet that stated, among that things, that "Dr. Stanton is ONLY here the first three Mondays of the month."

D. False Claims for Psychological Testing

330. As another source of revenue, CPI directed the MAs to perform psychological testing on patients purportedly to determine whether they were at risk of issues with addiction, depression, or suicidal thoughts.

331. Psychological tests at CPI consisted of an iPad questionnaire (approximately 50 questions) given, with very rare exception, to every non-self-pay patient at every visit regardless of condition, mental health history, general health history, or risk. The receptionist "administered" the psychological test when he or she handed the patient the iPad upon each patient's arrival. The patient finished the iPad questions and gave the iPad to the medical assistant. The medical assistant noted the numerical score, and the score was then entered into patient chart. No clinical decisions were based on this score, nor did most practitioners understand what the numbers indicated. Also, it was very common for scores from the last visit to be copied as the score for the next visit due to medical assistants being scolded for taking too long with individual patients (due to the psychological tests).

332. As stated above, patients' medical charts often had the indication "(y)," which told the urine drug test technician that the patient would get a full panel drug test. The "(y)" also indicated to the medical assistant that this patient needed a psychological test.

333. However, the field entitled "Psyc test results reviewed/recommendations" in most patients' medical charts was blank because CPI did not review the psychological test results, nor did CPI make any recommendations based on them. This practice demonstrates that most psychological tests were medically unnecessary.

334. The field entitled "Psyc Test" in the patients' medical charts showed psychological test score history. The CESD scores range from 0-60; the higher the score and the greater the risk, the greater the presence of depression symptoms. The PMQ scores range from 0-104, with low risk being 0-34, medium risk being 35-69, and high risk being 70-104. Higher scores are associated with a history of substance abuse, higher levels of psychosocial distress, and poorer functioning.

335. In the vast majority of cases, the COG scores are invalid. Medical assistants filled out the last section of each psychological test on their own because it is tedious and time consuming to administer this portion. Moreover, it would be impossible in the five minutes allotted per patient. This portion consists of eight questions to detect cognitive impairment (e.g., asks patients to repeat an address, recall today's date, recognize the correct time on various clocks, etc.). CPI asked these questions of patients only about 5% of the time. At other times, medical assistants simply answered all eight questions with the right answers, and patients would receive a perfect score for this section.

336. This behavior is not only fraudulent, but also unethical because cognitive impairment is something that CPI should actually monitor in patients that are taking narcotics/opioids long term. When the issue of the psychological tests was brought to management (as a defense to the medical assistants being accused of being "slow" and taking "too long"), instead of giving more time for medical assistants to complete the tests, Relator and other medical assistants were told to skip the last part (COG) and fill it out themselves. It was also common for a medical assistant to complete the entire test, either by clicking 0/does not apply/never repeatedly

to result in a low risk score, or by looking up previous medical tests and copying the individual answers to duplicate the score. This was done at the end of the day, at lunch, or while walking the chart through the back door to give to the nurse practitioner, due to the lack of time between patients.

337. CPI also used a Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP®-R) form, which was essentially a psychological test on paper given to some patients ahead of time. Using this form, some patients self-administered psychological testing for which CPI billed Government Healthcare Programs.

338. CPI billed Government Healthcare Programs for iPad-administered psychological tests under CPT codes 96102 and/or 96103.

339. Government Healthcare Programs only reimburse for certain psychological testing if it is medically necessary under CPT codes 96102 and/or 96103. The Medicare reimbursement for CPT code 96103 ranged from approximately $19.00 to approximately $50.00 per test during the relevant time period.

340. Relator was not aware of any response protocol in the event psychological issues were identified. Although medical assistants administered the tests, Relator saw no plan in place regarding suicidal ideation and no formal policy as to how to respond to the results of the iPad testing.

341. Medical records show that the Clinic Defendants billed the Government Healthcare Programs for psychological testing. The above facts demonstrate that the Clinic Defendants knew or should have known that the type of psychological testing CPI and its practitioners were performing was not reimbursable by the Government Healthcare Programs because it was not medically necessary and, even if necessary, was performed in a manner that made the testing worthless.

E. False Claims for Allergy Testing

342. The Clinic Defendants billed Government Healthcare Programs for allergy tests that lacked medical necessity and were upcoded.

343. Unqualified, untrained CPI employees administered and interpreted allergy tests.

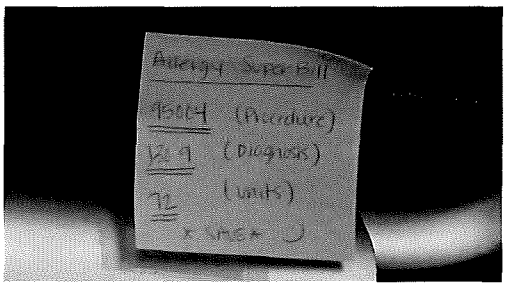
344. Adding to the egregiousness of the false billing, the Clinic Defendants further put patients at risk and cheated the Government by re-using allergy testing supplies but billing the Government as if new supplies were used for each test.

345. Medical assistants were told, and were all but forced, to coerce patients to get allergy tests, regardless of allergy history. CPI's consent form states that the allergy test is $300 without insurance; however, CPI charged insurance $779.04.

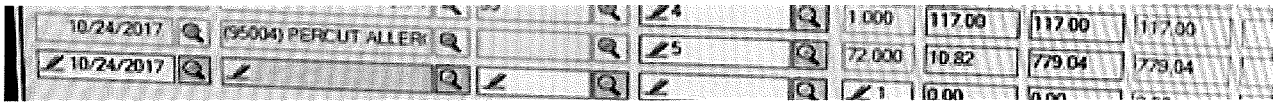
346. Under CPI policy, all patients were to get an allergy test on their second visit. Patients were told that this allergy test counted as an "adjunct therapy" required by the "state" for any pain management patient. This allergy test only tested for environmental allergens (pollen, grass, pets, mold, etc.) and did not test for medication or anything pertinent to pain management.

347. To ensure payment from third-party payors, CPI instructed medical assistants to bill the allergy tests using a false diagnosis of "Allergic Rhinitis" (J30.9) for each patient who consented to an allergy test, regardless of whether the patient had any allergy history. Most of the patients had no reaction to the test.

348. The photo below is of a sticky note titled "Allergy Super Bill" that was given to medical assistants, including Relator, as a cheat sheet on how to bill for allergy tests using procedure code 95004 and diagnosis code J30.9, and denoting "72" as the number of "units" (*i.e.*, the number of individual allergy tests being billed):



349. Billing in accordance with these instructions resulted in Government Healthcare Programs paying substantial sums of money for unnecessary and unreasonable allergy tests, as indicated by this photograph of CPI's billing for patient B.M.:



350. Patients' medical charts often had an "order" in the chief complaint section that directed medical assistants to give an allergy test ("FILL OUT AT PPWK"). However, the manager entered this notation on the charts, instead of the practitioner ordering it, as Medicare requires. CPI had a standing order for administration of allergy tests to virtually every patient. Many patients tried to refuse the allergy test, since it was unnecessary, and most patients were confused as to why CPI offered it. Medical assistants had to document this so that they would not be questioned after the fact as to why they did not do more allergy tests that day.

351. Relator was aware that CPI practitioners stated they had nothing to do with the allergy tests, which was the same reply Relator received from a nurse practitioner, Meghan Anderson, when Relator asked a question about the allergy tests. Practitioners did not discuss, diagnose, treat, or even address the results of the allergy tests. Patient charts show the allergy test given, but no additional results, follow up, paperwork, or even mention of the allergy test.

352. On two separate occasions, Relator witnessed patients having a relatively severe reaction to the allergens. However, no Benadryl or any type of treatment was given (or even available in the clinic at all) until Benadryl was kept in Relator's office beginning approximately two months after her request.

353. In order to keep up with the strict five-minute-per-patient cap with the medical assistant, patients were not scheduled for longer appointments when CPI was administering the allergy test. Instead, patients were returned to the lobby where they sat for 10 or 15 minutes, with all 71 allergens exposed on their forearms.

354. Many times, patients never signed consent forms for this procedure, due to medical assistants not having access to or copies of the consent form.

355. CPI management sent one employee home without pay as retaliation for not giving enough allergy tests, despite multiple employees stating that whether the patient consents to the allergy test is out of the employee's hands.

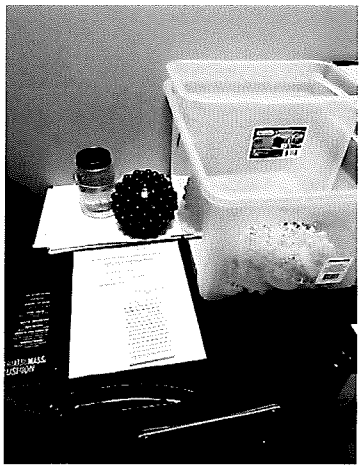
356. As the "Allergy Super Bill" shows, the Clinic Defendants falsely billed Government Healthcare Programs for allergy tests using CPT code 95004 (percutaneous tests (scratch, puncture, prick) with allergenic extracts, immediate type reaction, including test interpretation and report).

357. Percutaneous allergy tests are performed with allergenic extracts that provoke an immediate reaction. The skin is scratched, punctured, or pricked with one or more allergenic extracts. A physician or other qualified health care professional then observes and evaluates the test sites to identify any allergic reaction, such as redness and inflammation. The results are interpreted, and a written report is provided that specifies the number of allergens tested, the specific allergenic extracts used, and the absence/presence/degree of allergic reaction to each allergen.

358. Relator estimates that CPI administered more than 500 allergy tests without medical necessity under the guise of the false J30.9 diagnosis, for which CPI billed $779.04 per test.

359. CPI upcoded its billings for allergy tests by billing for 72 units, when only 71 units were allergens, and one was a control. This added to the falsity of the billings. The National Correct Coding Initiative Policy Manual for Medicare Services, as revised January 1, 2016, states: "Some allergy testing CPT codes (e.g., 95004, 95017-95052) are reported based on the number of individual tests performed. CMS payment policy does not allow including testing of positive or negative controls in the number of tests reported. For example, if percutaneous testing (CPT code 95018) with penicillin allergens administering six allergens plus a positive and negative control is performed, only six tests may be reported for CPT code 95018."

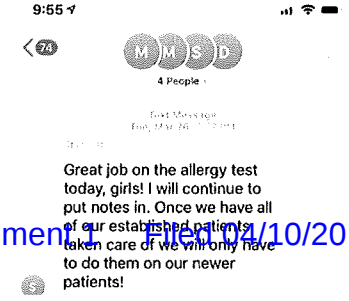
360. One CPI medical assistant, M.M., received $1,500 in total bonuses as a kickback for pushing the other medical assistants to administer allergy tests and assuring testing pricks were not thrown away. CPI's owners took the testing pricks home to be bleached and re-used as shown in the photographs below.



361. This pattern and practice of re-using pricks at the direction of CPI's owners is egregious misconduct that jeopardized the health and safety of patients and establishes the Clinic Defendants' knowledge of their misconduct with respect to allergy tests.

362. The Clinic Defendants' knowledge is also demonstrated by daily reports that were given to CPI's owners showing the number of allergy tests given that day. If any patients were not given the allergy testing, the owners demanded to know why and demanded proof that the patients signed the "declined" consent form.

363. On March 26, 2019, CPI owner Debbie Cox and manager Stacie Broadbent sent text messages of encouragement to Relator and others for doing allergy tests (see below). In her text, Broadbent stated: "I will continue to put notes in." This refers to the manager inputting *Allergy Test* or *FILL OUT "AT" PPWK* as patient chief complaints. These tests were not ordered by a physician or for any individualized medical purpose, but rather, as indicated in the text message, to "have all of [CPI's] established patients taken care of . . ."



364. Documentation obtained by Relator establishes that the Clinic Defendants billed Government Healthcare Programs for allergy tests for patients who had no medical necessity for the tests. These documents include the medical records for patients B.R., D.S., and D.L., described below.

F. Other False Claims (Compounded Medications/Pain Creams/DME)

365. Relator also observed that a majority of CPI patients were prescribed pain cream as a required adjunct therapy. Patients were not really given a choice as to where to fill these prescriptions. The creams were filled at the on-site Cox Family Pharmacy and brought to the office for the patients scheduled for the day. The receptionist would collect the co-pays and record them on a daily leger.

366. Compound medications are specially formulated, personalized medications prepared by licensed pharmacists for individual patients for whom commercially manufactured medications are unavailable or unsuitable for one reason or another. Because of the individualized formulation, reimbursement rates for compounded prescriptions are relatively high.

367. The Pharmacy Defendants submitted or caused to be submitted claims to Government Healthcare Programs for compounded prescriptions that were issued without regard to whether beneficiaries needed them and that were, in fact, medically unnecessary.

368. In addition, Defendants' use of the Cox Family Pharmacy violates Tennessee law prohibiting owners of pain management clinics from locating or participating in locating a pharmacy in which any owner of the pain management clinic has an ownership interest adjacent to the clinic. Tenn. Code Ann. § 63-1-316(h). "Adjacent" means "within 1,000 feet." Tenn. Comp. 7 Rule and Reg. 1200-34-01-.01(2).

369. Documentation obtained by Relator also establishes the lack of medical necessity for durable medical equipment, such as back braces, for which Defendants billed, as discussed below. These documents include the medical records for patients D.S. and J.P., described below.

G. Examples of False Claims

370. Below are representative examples of patients whose records show that Defendants falsely billed Government Healthcare Programs for urine drug testing, injections, psychological testing, allergy testing, and durable medical equipment.

1. Patient A.H.

371. Treated at CPI on January 28, 2019, Patient A.H.[20] had TRICARE and private insurance (through Aetna). Patient A.H.'s chart indicates that s/he presented for a joint injection and a consult.

372. Patient A.H.'s medical record states: "**Risk Assessment**: Low risk for potential medication misuse or abuse due to low MED, we will continue with POC [point of care] at all visits and definitive UDS [urine drug screen] at least 4 times per year, testing will be performed in Jan, Jun, Sept, and Dec, in 2018, patient is not aware of schedule. *Definitive drug screen is required to confirm the presence of medication metabolites and to obtain an accurate measurement of the amount of medication and metabolites in the patient's urine. Obtaining this information is imperative in the treatment of this patient to ensure that the medication is being taken as prescribed, detect any possible medication diversion, and ensure the urine is not altered.*"

373. Patient A.H., whom Defendants admitted is "low-risk for medication misuse or abuse," did not need a full, definitive urine drug test every quarter, and there is no medical

[20] For privacy, HIPAA, and PHI reasons, Relator identifies these patients by only their initials in this Complaint.

necessity for both a POC *and* a definitive urine drug test for patient A.H. In addition, it is not proper or necessary to order a full, definitive urine drug test prospectively without regard to the patient's future condition or behavior at those visits.

374. The field entitled "Psyc test results reviewed/recommendations" in patient A.H.'s medical chart was blank because, for this patient and most others, CPI did not review the psychological test results, nor did CPI make any recommendations based on them. Patient A.H. in particular scored very high in the depression section (CESD) for the past two visits. However, CPI continued to prescribe opioids to this potentially depressed patient, demonstrating both recklessness and that the psychological test was medically unnecessary.

2. Patient B.F.

375. The medical chart for patient B.F., seen at CPI on March 5, 2019, is another example of unnecessary psychological testing. The subjective portion of patient B.F.'s chart shows that CPI practitioners were suddenly beginning to insert their "interpretations" as wnl (within normal limits). These abrupt changes to charting habits were CPI's response to increased rejection of the claims due to lack of documentation or increased scrutiny into the high volume of claims. This chart also shows that CPI practitioners had no actual knowledge of these tests and what the results indicated. Upon information and belief, CPI practitioners never reviewed the results of the 50-question psychological test administered by the MA contained, as indicated by the interpretation of the COG: 9 result "moderate risk for cognitive impairment; discussed with pt and will continue to monitor." This interpretation is false as a score of 9 is a perfect score on the COG scale, so the risk is not moderate. Rather, it is low, and there would be nothing to discuss with the patient.

3. Patient B.R.

376. The chart for Patient B.R., a Medicare beneficiary seen at CPI on April 2, 2019, states "med 15" as the chief complaint, which indicates she is a Medicare patient with a $15 copay.

377. The chart also states "AT: 03/296[sic]/17," which stands for allergy test. This indicates that patient B.R. had (and was billed for) an allergy test, despite having no allergies (other than aspirin).

378. Patient B.R.'s medical chart states: "**Risk assessment**: high risk for potential medication misuse or abuse due to MED. We will perform definitive lab at all appointments. *Definitive drug screen is required to confirm the presence of medication metabolites and to obtain an accurate measurement of the amount of medication and metabolites in the patient's urine. Obtaining this information is imperative in the treatment of this patient to ensure that the medication is being taken as prescribed, detect any possible medication diversion, and ensure the urine is not altered.*" However, it is not proper or necessary to order a full, definitive urine drug test prospectively at every visit without regard to the patient's future condition or behavior at those visits.

379. Patient B.R.'s chart indicates CPI performed psychological testing on February 5, 2019. Even though no scores were reported, CPI still billed for the psychological test. Patient B.R. was low risk, yet CPI repeated testing every 28 days.

380. Gaps in testing indicate that the medical assistant either failed to record the score, which happens frequently, or the test was never administered due to time constraints. Nurse practitioners did not know whether patients got the psychological test, and since they did not look at the results anyway, they did not even notice when they were omitted.

381. Patient B.R. also never had any indications that a psychological evaluation or test should be administered, as his/her results are constantly within the low risk category. Psychological testing is only to be ordered as an initial screening for new patients and then as needed, decided at the discretion of the practitioner. It is not appropriate, as CPI did, to implement a standing order to give every non-self-pay patient a psychological test at every visit.

4. Patient C.H.

382. Patient C.H., a Medicare beneficiary, was seen at White House Pain Institute on February 19, 2019. Patient C.H.'s chart states: "**Risk Assessment**: High risk for potential

medication misuse or abuse due to MEDD and history of inconsistent uds. We will perform definitive uds with each visit." The chart also states: "*Definitive drug screen is required to confirm the presence of medication metabolites and to obtain an accurate measurement of the amount of medication and metabolites in the patient's urine. Obtaining this information is imperative in the treatment of this patient to ensure that the medication is being taken as prescribed, detect any possible medication diversion, and ensure the urine is not altered.*" However, it is not proper or necessary to order a full, definitive urine drug test prospectively at every visit without regard to the patient's future condition or behavior at those visits.

383. Patient C.H.'s medical record also states: "(M47.812) spondylosis w/o myelopathy." The Clinic Defendants and the Lab Defendants instructed Relator to add this diagnosis code to any lumbar medial branch block injection, cervical medial branch block injection, or thoracic medial branch block injection in order for Government Healthcare Programs to approve the claims. The addition of this code was not done at the direction of an appropriate clinician and did not have any clinical or medical necessity. It was falsified solely to obtain payment from Government Healthcare Programs and other third-party payors.

5. Patient D.S.

384. According to the medical chart for patient D.S., a Medicare beneficiary, Medicare paid "1045.74 FOR LSO/MB." LSO, which stands for lumbar sacral orthosis, is another term for back brace, sometimes also shorthanded. These very expensive back braces were prescribed per a standing order. They were also "fitted" by un-trained medical assistants. Multiple patients complained of not getting back braces, but their charts and billing reflected that they did. An OIG report[21] details the proper billing procedures and documentation for LSOs, which CPI did not follow.

385. The "Major Events" section in patient D.S.'s medical chart indicates this patient received an allergy test, which was not needed because D.S. was being treated for back pain.

6. Patient D.L.

[21] *See* https://oig.hhs.gov/oas/reports/region9/91703027.pdf (last accessed April XX, 2020).

386. The patient chart for patient D.L., a Medicare beneficiary whom CPI treated on April 9, 2019, shows the "order" in the chief complaint that directed medical assistants to give an allergy test ("FILL OUT AT PPWK").

387. Patient D.L.'s chart also states: "**Risk Assessment**: Medium risk due to new patient status. UDS will be performed 8 times per year: **January, February, March, May, July, September, October, and November**. *Definitive drug screen is required to confirm the presence of medication metabolites and to obtain an accurate measurement of the amount of medication and metabolites in the patient's urine. Obtaining this information is imperative in the treatment of this patient to ensure that the medication is being taken as prescribed, detect any possible medication diversion, and ensure the urine is not altered.*" The simple fact that a patient is new does not justify eight full urine drug test panels per year, ordered in advance. It is not proper or necessary to order a full, definitive urine drug test prospectively, especially so frequently, without regard to the patient's future condition or behavior at those visits.

7. Patient T.H.

388. The medical record for patient T.H., a TennCare beneficiary, states: "**Risk Assessment**: High risk according to clinic policy for opioid misuse d/t MED therefore a definitive lab with mass spec is necessary each visit. This patient is a chronic pain patient that is using opiates/opioids and or on other schedule 2 and 3 medications. Because of the risk of abuse with other prescribed medications of the same nature not prescribed by this clinic and illicit drugs of abuse, I am ordering this drug test out of medical necessity for this patients [sic] safety and efficacy and to prevent to the best of my ability this patient to abuse any prescribed or illicit/illegal drugs." Patient T.H.'s record also states: "Definitive drug screen is required to confirm the presence of medication metabolites and to obtain an accurate measurement of the amount of medication and metabolites in the patient's urine. Obtaining this information is imperative in the treatment of this patient to ensure that the medication is being taken as prescribed, detect any possible medication diversion, and ensure the urine is not altered."

389. However, it is not proper or necessary to order a full, definitive urine drug test prospectively at every visit without regard to the patient's future condition or behavior at those visits.

8. Patient T.J.

390. The medical record for patient T.J., a Medicare beneficiary seen on January 28, 2019, states: "**Risk Category**: High risk for potential medication misuse or abuse due to inconsistent UDS and overtaking medication and MED level. We will perform POC [point of care] and UDS at all appointments. This patient is a chronic pain patient that is using opiates/opioids and or on other schedule 2 and 3 medications. Because of the risk of abuse with other prescribed medications of the same nature not prescribed by this clinic and illicit drugs of abuse, I am ordering this drug test out of medical necessity for this patients safety and efficacy and to prevent to the best of my ability this patient to abuse any prescribed or illicit/illegal drugs." Patient T.J.'s medical chart also states: "Definitive drug screen is required to confirm the presence of medication metabolites and to obtain an accurate measurement of the amount of medication and metabolites in the patient's urine. Obtaining this information is imperative in the treatment of this patient to ensure that the medication is being taken as prescribed, detect any possible medication diversion, and ensure the urine is not altered." However, it is not proper or necessary to order a full, definitive urine drug test prospectively at every visit without regard to the patient's future condition or behavior at those visits. In addition, there is no medical necessity for both a POC and a definitive urine drug test.

9. Patient V.O.

391. The medical record for Patient V.O., a Medicare Advantage beneficiary seen on March 25, 2019, states: "**Risk Assessment**: med/high; due to age and history of inconsistency UDS 2019: Mar, May, June, July, Oct, Dec … *Definitive drug screen is required to confirm the presence of medication metabolites and to obtain an accurate measurement of the amount of medication and metabolites in the patient's urine. Obtaining this information is imperative in the treatment of this patient to ensure that the medication is being taken as prescribed, detect any*

possible medication diversion, and ensure the urine is not altered." However, it is not proper or necessary to order a full, definitive urine drug test prospectively, especially so frequently, without regard to the patient's future condition or behavior at those visits.

392. Patient V.O.'s medical chart also states: "patient cannot explain the Xanax." This demonstrates that the urine drug test was clinically irrelevant, since Defendants gave or caused patient V.O. to receive the same prescription, despite the clinical finding of unprescribed Xanax.

393. Patient V.O. was prescribed pain cream.

10. Patient J.K.

394. According to a CMS 1500 relative to patient J.K., on July 5, 2017, CPI billed TennCare for services rendered to patient J.K. on June 27, 2017. Box 24 on the front of the CMS 1500 states that CPI billed TennCare for, among other things, one unit each of CPT code 80307 (a presumptive/qualitative drug test) and CPT code G0483 (a definitive/quantitative drug test for 22 or more drug types), the highest-paying code in the G0480-G0483 series.

395. On the front of the CMS 1500, in box 31, Edith Dean, a nurse practitioner, signed this statement: "I certify that the statements on the reverse apply to this bill and are made a part thereof." The reverse of the form states: "I certify that the services listed above were medically indicated and necessary to the health of this patient . . . [and] that the foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from Federal and State funds and that any false claims, statements, or documents, or concealment of a material fact may be prosecuted under applicable Federal or State laws."

396. Common practice in the medical community is to first order a qualitative test of urine to detect the presence or absence of drugs or metabolites in the sample. Depending on the initial results from the qualitative testing, it may, in some instances, be medically appropriate to next perform a quantitative drug test to determine the concentration of specific drugs in a patient's system. The purpose of quantitative testing is to confirm any positive results from the qualitative test and to determine the concentration of the specific drug(s) present.

397. In most cases, quantitative testing is limited to clinical situations where qualitative testing has been performed and the results of that test indicate that quantitative tests for particular drugs are needed.

398. It was not reasonable, medically indicated, or medically necessary to perform and bill for a full, definitive urine drug test and a presumptive/qualitative drug test for patient J.K. on the same day.

11. Patient B.M.

399. According to a CMS 1500 relative to patient B.M., on June 14, 2017, CPI billed TennCare for services rendered to patient B.M. on May 31, 2017. Box 24 on the front of the CMS 1500 states that CPI billed TennCare for, among other things, one unit each of CPT code 80307 (a presumptive/qualitative drug test) and CPT code G0483 (a definitive/quantitative drug test for 22 or more drug types), the highest-paying code in the G0480-G0483 series.

400. On the front of the CMS 1500, in box 31, Erin Gardiner, a nurse practitioner, signed this statement: "I certify that the statements on the reverse apply to this bill and are made a part thereof." The reverse of the form states: "I certify that the services listed above were medically indicated and necessary to the health of this patient . . . [and] that the foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from Federal and State funds and that any false claims, statements, or documents, or concealment of a material fact may be prosecuted under applicable Federal or State laws."

401. Common practice in the medical community is to first order a qualitative test of urine to detect the presence or absence of drugs or metabolites in the sample. Depending on the initial results from the qualitative testing, it may, in some instances, be medically appropriate to next perform a quantitative drug test to determine the concentration of specific drugs in a patient's system. The purpose of quantitative testing is to confirm any positive results from the qualitative test and to determine the concentration of the specific drug(s) present.

402. In most cases, quantitative testing is limited to clinical situations where qualitative testing has been performed and the results of that test indicate that quantitative tests for particular drugs are needed.

403. It was not reasonable, medically indicated, or medically necessary to perform and bill for a full, definitive urine drug test and a presumptive/qualitative drug test for patient B.M. on the same day.

12. Patient S.W.

404. The medical record for patient S.W., a Medicare Advantage patient, states: "back brace: has one, doesn't use it much." However, patient S.W.'s medical record also states: "back brace ordered 02/05/2019." This is another example of medically unnecessary durable medical equipment for which there was no clinical indication.

405. Patient S.W. was prescribed pain cream "in office to take next door."

13. Patient G.W.

406. According to a CMS 1500 relative to patient G.W., on August 8, 2017, CPI billed TennCare for services rendered to patient G.W. on July 20, 2017. Box 24 on the front of the CMS 1500 states that CPI billed TennCare for, among other things, one unit each of CPT code 80307 (a presumptive/qualitative drug test) and CPT code G0483 (a definitive/quantitative drug test for 22 or more drug types), the highest-paying code in the G0480-G0483 series.

407. On the front of the CMS 1500, in box 31, Erin Gardiner, a nurse practitioner, signed this statement: "I certify that the statements on the reverse apply to this bill and are made a part thereof." The reverse of the form states: "I certify that the services listed above were medically indicated and necessary to the health of this patient . . . [and] that the foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from Federal and State funds and that any false claims, statements, or documents, or concealment of a material fact may be prosecuted under applicable Federal or State laws."

408. Common practice in the medical community is to first order a qualitative test of urine to detect the presence or absence of drugs or metabolites in the sample. Depending on the

initial results from the qualitative testing, it may, in some instances, be medically appropriate to next perform a quantitative drug test to determine the concentration of specific drugs in a patient's system. The purpose of quantitative testing is to confirm any positive results from the qualitative test and to determine the concentration of the specific drug(s) present.

409. In most cases, quantitative testing is limited to clinical situations where qualitative testing has been performed and the results of that test indicate that quantitative tests for particular drugs are needed.

410. It was not reasonable, medically indicated, or medically necessary to perform and bill for a full, definitive urine drug test and a presumptive/qualitative drug test for patient G.W. on the same day.

G. Defendants Retaliated Against Relator for Challenging Conduct that Violates Federal and State False Claims Acts

411. In her first week (starting August 22, 2018) as a Medical Assistant (MA) at CPI, Relator Nicholson was trained by two co-workers (M.M. and M.H.[22]) who were held out as "medical assistants" although neither had MA certification or training. Fortunately, Relator was already licensed and certified as an EMT, and this, combined with her undergraduate B.S. degrees in public health and biology, gave her a foundation from which to learn quickly.

412. During her tenure at CPI, Relator's managers included Kodie Morrison, Zachary Otts, Megan Rabbitt, and Stacie Broadbent.

413. On Relator's third day of employment, M.M. told Relator that the only way to stick around was to "keep your head down and do what you are told" and "don't question anything Michael, Debbie, or Megan says, even if it's sketchy." These comments were references to Defendants Michael and Debbie Cox and CPI's billing manager, Megan Rabbitt. M.M. further told Relator that such challenges would lead these same people to conclude she is not "on the same boat" with them and could result in termination.

[22] Names of non-manager CPI employees can be made available if needed.

414. Relator was initially skeptical of these comments, but with time, came to understand and agree with M.M.'s assessment. Relator heard Defendant Michael Cox often respond to questions about how things were done with words to the effect: "If I were you, I wouldn't question the person who writes your paycheck" or "a smart person wouldn't question the person writing your paycheck."

415. Relator soon learned that CPI was not focused on providing quality care to its patients and cut corners in many ways. She received little assistance in learning how to do proper charting for patients. She also was alarmed that CPI maintained a strict five-minute maximum per patient. During that time, medical assistants were expected to (1) take and record vitals; (2) administer psychological testing; (3) verify patient pill bottles against the Tennessee Controlled Substance Monitoring Database and count any remaining pills; (4) record and chart the subjective, objective, and plan portion of the patient chart, which included asking over 30 questions of the patient; (5) administer "allergy" testing on every patient (except self-pay patients); and (6) fit the patient for a back/knee/wrist brace if noted in the chart.

416. The only vitals actually taken were blood pressure (using cheap automatic devices that rarely worked correctly), pulse, and weight (if the urine drug test technician remembered). CPI did not use pulse oximeters at all. Relator observed that medical assistants frequently just copied vitals from the previous visit or recorded a predetermined number as instructed by M.M. For example, Relator was directed to record respirations of 12 breaths per minute (bpm) for every patient at every visit. This is a clear falsification of medical records since many of CPI's patients have COPD or are on oxygen, to say nothing of the patients' condition as they are being rushed from place to place at CPI. This practice also concerned Relator because, with very rare exception, all patients were taking opioids, which have the very serious, life-threatening side effect of respiratory depression.

417. Relator made efforts to improve the quality of care. For example, given the poor quality of the automatic blood pressure devices, Relator offered to teach the medical assistants

how to use manual blood pressure cuffs. Her efforts were brushed off by then-general manager Kodie Morrison, who said "don't worry about it; it's not like the providers check anyway."

418. In mid-January 2019, Rabbitt wrongly accused Relator of billing incorrectly, as discussed above at paragraphs 306-312, and Relator said she would not bill the way CPI had "always done it." Relator then began to experience increased tension and hostility toward her in her workplace.

419. About a week after her conversation with Rabbitt, Relator approached Michael Cox about the coding issue and the hostility she was experiencing. She told Cox it wasn't her intention to step on any toes, but Rabbitt was punishing her as if she had done something wrong by bringing the billing issue to Rabbitt's attention. Relator told Cox that Rabbitt's directions about billing were against Medicare guidelines. She further said that she intended to continue billing the right way. Cox told Relator he'd "look into it" to be sure the coding was correct and assured her he would address the work environment. However, he never got back to Relator about the coding.

420. The hostility continued and escalated, including petty and intimidating treatment by Rabbitt. Relator did not feel she could talk about this treatment with Stacie Broadbent, her then-manager. Broadbent had a strong friendship with and loyalty to Rabbitt, and other employees had warned Relator not to share anything regarding Rabbitt with Broadbent.

421. Because the environment was making it hard for Relator to work, she again reported the retaliatory treatment to Michael Cox sometime between early March and her termination. But nothing changed.

422. Relator worked with a nurse practitioner (J.P.) whom she respected and viewed as a mentor. J.P. also resisted the illegal conduct that Relator was observing. As a result, Rabbitt challenged J.P. about billing as well. When J.P. objected to what Rabbitt was asking her to do, Michael Cox put J.P. down, saying "just keep the peace and stop butting heads with Megan."

423. CPI terminated J.P. suddenly in mid-April. Relator went in and talked to Michael Cox on J.P.'s behalf. She told him that Rabbitt's view of J.P. was wrong and that J.P. worked hard

for the good of the patients and the company. Cox brushed off her comments, saying that he "doesn't get into all this drama."

424. In early April, Michael Cox directed Relator to train M.H. to assist with fluoroscopy injections and do billings. Relator asked Michael Cox if her head was on the chopping block, too. He claimed Relator was training M.H. as a "back-up." Relator proceeded to train M.H. as directed, but correctly suspected that her days were numbered at CPI.

425. On April 17, Relator was reviewing patient charts. Before looking at any specific charts, she noticed something peculiar—Michael Cox was listed as a patient numerous times. Although the charts named Michael Cox as the patient who received certain injections, the chief complaint area of the record had a different patient's name and date of birth. This was highly unusual and pointed to likely wrongdoing, such as giving patients injections under Michael Cox's insurance, or simply billing for injections that never happened. When she saw these anomalies, she stopped reviewing the records. Relator knew that her manager frequently checked the logins to the electronic health records, and she was concerned CPI would terminate her if they knew what she had seen. Relator did not open the chart with Michael Cox's name, fearing that she had already drawn enough attention by simply seeing it. CPI terminated her the next day.

426. At 7:13 in the morning of April 18, Relator texted Broadbent and "called out" sick because she was distraught about what she had seen the previous day and did not feel she could effectively work with patients that day. This was only the second time she had called out sick in eight months.

427. Broadbent did not respond until 12:19 p.m., saying "ok, hope you're feeling better soon."

428. Just about an hour later, at 1:33 p.m., Broadbent texted Relator and said "Unfortunately due to you calling out and showing up late for work I have came [sic] to the decision that it is best to let you go. Michael will have your final check deposited to your bank."

429. At about 2 p.m. Relator drove to the office and retrieved her personal belongings. She briefly encountered Broadbent who merely said "hello." Relator then left.

430. About a week later, on April 24, 2019, Relator's husband Zachary "Tyler" Nicholson subsequently went to CPI to return some documents that Relator had inadvertently packed with her personal belongings.

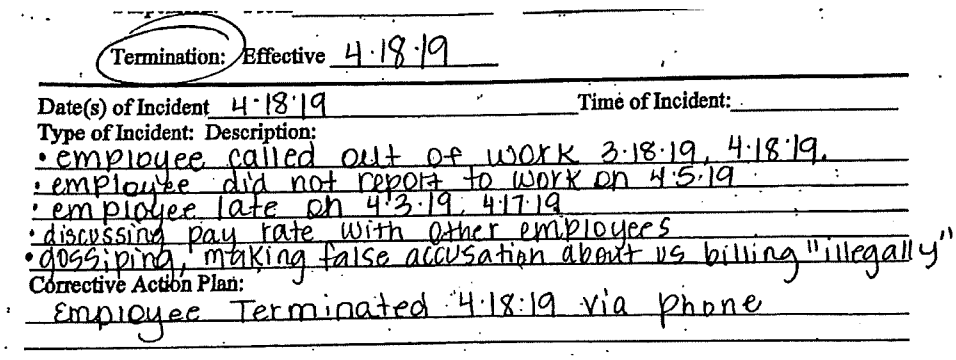
431. When he arrived, Tyler Nicholson was taken to Michael Cox's office where they engaged in a lengthy conversation. Among other things, Michael Cox told him that:

- employees call out sick all the time, including a new employee who had already called out twice;
- calling out sick was not the reason for Relator's termination;
- CPI has a policy allowing five call outs;
- Relator's performance was "absolutely not" the reason for her termination; and
- Relator was terminated for discussing and complaining about pay with another employee.

432. Michael Cox also told Tyler Nicholson that it was brought to his attention that Relator was "fudging her numbers" on her timesheets. When Nicholson asked Cox the basis for this claim, Cox asked Broadbent, who provided only vague references to text messages and other employees in the office.

433. Tyler Nicholson asked Michael Cox for a copy of Relator's personnel file and her timesheets. Cox said that it would take some time to assemble Relator's timesheets, but asked Broadbent for the employee file. Broadbent brought it to him, but said that she had "one more thing to add." Then Nicholson observed that Broadbent was preparing a Disciplinary Action Form for Relator. Broadbent signed and fraudulently dated the form 4/18/2019. She then made a copy of the form for Nicholson before he left CPI.

434. In the backdated Disciplinary Action Form, CPI directly admitted that it terminated Relator for reporting that the company was illegally coding injections—that is, it stated that Relator was "gossiping, making false accusations about [CPI] billing 'illegally.'"



Termination: Effective 4·18·19

Date(s) of Incident 4·18·19 Time of Incident:

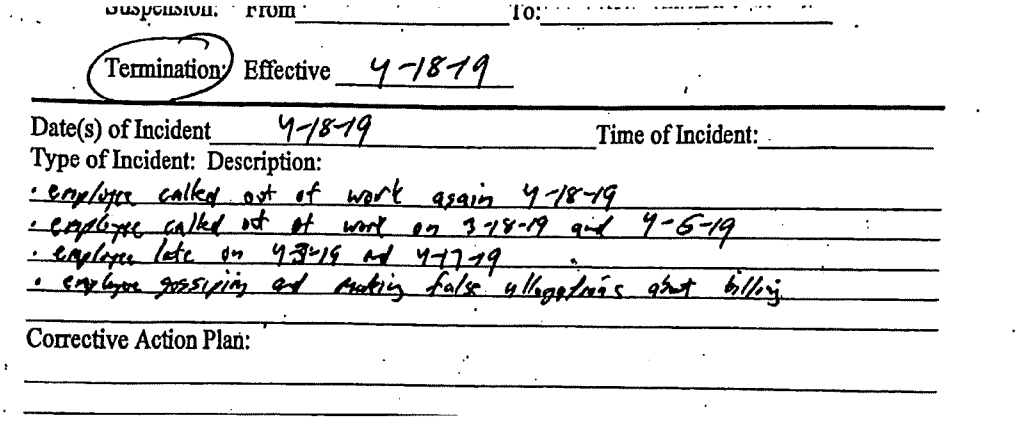
Type of Incident: Description:

- employee called out of work 3·18·19, 4·18·19.
- employee did not report to work on 4·5·19
- employee late on 4·3·19, 4·17·19
- discussing pay rate with other employees
- gossiping, making false accusation about us billing "illegally"

Corrective Action Plan:

Employee Terminated 4·18·19 via phone

435. A second Disciplinary Action Form confirmed that CPI terminated Relator for "making false allegations about billing."



Suspension: From To:

Termination Effective 4-18-19

Date(s) of Incident 4-18-19 Time of Incident:

Type of Incident: Description:

- employee called out of work again 4-18-19
- employee called out of work on 3-18-19 and 4-5-19
- employee late on 4-3-19 and 4-17-19
- employee gossiping and making false allegations about billing

Corrective Action Plan:

436. As stated above, CPI had never provided Relator with any reliable basis on which to conclude that her accusations about CPI's billing practices were false and that her research on the issue was incorrect.

437. The backdated Disciplinary Action claimed additional reasons for Relator's termination, all of which are pretexts for its actual admitted reason—Relator reported and refused to participate in CPI's illegal coding practices.

438. CPI's Disciplinary Action Form claimed Relator was terminated for absences and tardiness, but her attendance was within CPI policy guidelines, one claimed absence was for a day Relator was not scheduled to work, and other employees with similar or worse attendance were not terminated. The form claimed she had discussed her pay with other employees, but there was no stated policy prohibiting this, and hourly pay for various positions was commonly known at CPI.

439. Following her termination, Relator applied for unemployment benefits, which were initially denied because CPI claimed she was discharged for unacceptable attendance.

440. Relator appealed the denial of unemployment benefits. In the hearing, CPI was represented by Debbie Cox and Broadbent. Cox claimed that Relator was terminated for excessive absences. Relator explained why this accusation was untrue, including that a new employee who had been there just a month and a half had already called out three times, while she had called out just twice in about eight months. Relator further stated that her timecards would verify that she had been late by 10-15 minutes only about three times during her nine months at the company. Cox unsuccessfully tried to justify Relator's termination by claiming that other employees had better reason to call out because Relator doesn't have any children. Cox further claimed falsely that they had a restraining order against Nicholson, who Cox claimed was unstable and needed psychological help. The Judge was not persuaded by CPI's presentation and awarded Relator unemployment benefits.

441. As a result of CPI's treatment and ultimate termination of Relator, she has suffered damages. Despite diligent efforts, Relator has been unable to find comparable work. She has experienced lost backpay and anticipates ongoing wages losses in the future. She has experienced emotional distress, including the stress and anxiety of being treated with hostility while still employed, and the trauma of being unfairly terminated for doing the right thing. Her emotional distress has caused nausea, oversleeping, depression, and interference with relationships. She has experienced panic attacks and anxiety that she never had before. Her job loss has created ongoing financial stress. Relator's experiences at CPI have disillusioned her and sabotaged her career

aspirations. She was passionate about working in the medical profession, but the violation of patient trust she experienced at CPI has made her seriously question that aspiration—another source of depression and anxiety. Relator anticipates that the traumatic impact of her termination will be long-lasting professionally, financially, and emotionally.

442. CPI's retaliation against Relator was intentional, fraudulent, malicious, and reckless. CPI directly admitted that it terminated Relator because she reported illegal conduct. Relator reported malicious treatment while still employed, and nothing was done to curb that. She also refused to engage in illegal upcoding. CPI directed Relator to train her replacement and then terminated her, using additional false statements to justify its conduct. This egregious conduct warrants an award of punitive damages.

VII. CAUSES OF ACTION

Count 1
Federal FCA: Presentation of False Claims
(31 U.S.C. § 3729(a)(1)(A))

443. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented to the United States materially false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

444. As detailed above, the United States would not otherwise have paid for these false and fraudulent claims.

445. As a result of Defendants' actions, the United States has been, and may continue to be, severely damaged.

Count 2
Federal FCA: Using False Statements to Get False Claims Paid
(31 U.S.C. § 3729(a)(1)(B))

446. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used, or caused to be made or used false records or statements material to the payment of false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(1)(B).

447. Defendants' false certifications and representations were made for the purpose of ensuring that the United States paid the false or fraudulent claims, which was a reasonable and foreseeable consequence of Defendants' statements and actions.

448. The false certifications and representations made or caused to be made by Defendants were material to the payment of the false claims by the United States.

449. The United States, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these records or statements, paid false or fraudulent claims.

450. As a result of Defendants' actions, the United States has been, and may continue to be, severely damaged.

Count 3

Federal FCA: False Record Material to Obligation to Pay
(31 U.S.C. § 3729(a)(1)(G))

451. As detailed above, Defendants knowingly made, used, and/or caused to be made or used, false records or statements material to an obligation to pay or transmit money or property to the Government, and/or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government, in violation of 31 U.S.C. § 3729(a)(1)(G).

452. An "obligation" includes "an established duty, whether or not fixed, arising from an express or implied contractual ... relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment," 31 U.S.C. § 3729(b)(3), including "any overpayment [from Medicare] retained by a person after the deadline for reporting and returning an overpayment." 79 Fed. Reg. 29,843, 29,918 (May 23, 2014).

453. An "overpayment" is defined as "any funds that a person receives or retains under [the Medicare and Medicaid statutes] to which the person, after applicable reconciliation, is not entitled." 42 U.S.C. § 1320a–7k(d)(4)(B).

454. The PPACA requires a person who receives an overpayment of Medicare or Medicaid funds to report and return the overpayment within 60 days of the date on which the overpayment was identified. 42 U.S.C. § 1320a–7k(d)(1)–(2).

455. By knowing they had over-billed, yet failing to self-disclose the misconduct to Government Healthcare Programs or to refund the excessively billed and paid amounts, Defendants violated 31 U.S.C. § 3729(a)(1)(G).

456. As a result of Defendants' actions, the United States has been, and may continue to be, severely damaged.

Count 4

Tennessee FCA and/or Tennessee Medicaid FCA

(Tenn. Code Ann. §§ 4-18-103(a)(1), (2), (7), and (8) and/or 71-5-182(a)(1)(A), (B), and (D))

457. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented false or fraudulent claims for payment or approval, in violation of Tenn. Code Ann. § 4-18-103(a)(1) and/or § 71-5-182(a)(1)(A).

458. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false or fraudulent claim paid or approved by the State of Tennessee and/or its political subdivisions, in violation of Tenn. Code Ann. § 4-18-103(a)(2) and/or § 71-5-182(a)(1)(B).

459. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid or decrease an obligation to pay or transmit money to the State of Tennessee and/or its political subdivisions, in violation of Tenn. Code Ann. § 4-18-103(a)(7) and/or § 71-5-182(a)(1)(D).

460. At minimum, Defendants were the beneficiaries of inadvertent submissions of false claims, and failed to disclose the false claims to the State of Tennessee and/or its political subdivisions within a reasonable time after discovery of the false claims, in violation of Tenn. Code Ann. § 4-18-103(a)(8).

461. The State of Tennessee and/or its political subdivisions, unaware of the falsity of the claims and/or statements made, or caused to be made, by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for benefits funded by the State of Tennessee and/or its political subdivisions.

462. As a result of Defendants' actions, the State of Tennessee and/or its political subdivisions have been, and may continue to be, severely damaged.

Count 5
FCA: Retaliation against Defendants CPI and PIN
(31 U.S.C. § 3730(h))

463. Defendants unlawfully threatened, harassed, disciplined, and discharged Relator in retaliation for her lawful acts on behalf of the United States and the general public in furtherance of an action under the FCA and other efforts to stop one or more violations of the FCA. Defendants violated 31 U.S.C. § 3730(h)(1) when they retaliated against Relator for exercising her rights under the FCA.

464. As a direct result of Defendants' unlawful retaliatory conduct, including her termination, Relator has experienced damages for which she is entitled to relief under 31 U.S.C. § 3730(h)(2).

Count 6
Tennessee FCA: Retaliation against Defendants CPI and PIN
(Tenn. Code Ann. § 4-18-105)

465. Defendants unlawfully threatened, harassed, disciplined, and discharged Relator in retaliation for her lawful acts on behalf of the State of Tennessee and the general public in furtherance of an action under the TFCA and other efforts to stop one or more violations of the TFCA. Defendants violated Tenn. Code Ann. § 4-18-105(b) when they retaliated against Relator for exercising her rights under the TFCA.

466. As a direct result of Defendants' unlawful retaliatory conduct, including her termination, Relator has experienced damages for which she is entitled to relief under Tenn. Code Ann. § 4-18-105(c).

467. Clear and convincing evidence shows that Defendants' unlawful retaliatory conduct, including her termination, was malicious, intentional, fraudulent, and reckless, entitling Relator to punitive damages under Tenn. Code Ann. § 29-39-104.

Count 7

Tennessee Medicaid FCA: Retaliation against Defendants CPI and PIN
(Tenn. Code Ann. § 71-5-183(g))

468. Defendants unlawfully threatened, harassed, disciplined, and discharged Relator in retaliation for her lawful acts on behalf of the State of Tennessee and the general public in furtherance of an action under the TMFCA and other efforts to stop one or more violations of the TMFCA. Defendants violated Tenn. Code Ann. § 71-5-183(g) when they retaliated against Relator for exercising her rights under the TMFCA.

469. As a direct result of Defendants' unlawful retaliatory conduct, including her termination, Relator has experienced damages for which she is entitled to relief under Tenn. Code Ann. § 71-5-183(g).

Count 8

Tennessee Public Protection Act: Retaliation against Defendants CPI and PIN
(Tenn. Code Ann. § 50-1-304)

470. Defendants unlawfully discharged Relator in retaliation for her lawful acts on behalf of the United States and the general public, consisting of refusing to participate in and refusing to remain silent about, illegal activities in violation of the criminal or civil codes of the

State of Tennessee and the United States, and regulations intended to protect the public health, safety or welfare, including but not limited to violations of the FCA, 31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(1)(B), supporting regulations, the TMFCA, Tenn. Code Ann. § 4-18-103(a)(1), (2), (7), and the TMFCA, Tenn. Code Ann. §§ 71-5-182(a)(1)(A), (B), (D). Defendants violated Tenn. Code Ann. § 50-1-304 when they retaliated against Relator for refusing to participate in, or for refusing to remain silent about, Defendants' illegal activities.

471. As a direct result of Defendants' unlawful retaliatory conduct, Relator has experienced damages for which she is entitled to relief under Tenn. Code Ann. § 50-1-304(c).

WHEREFORE, Plaintiff/Relator Krista Nicholson requests that this Court:

As to the FCA Claims:

a. order, pursuant to 31 U.S.C. § 3729(a), Defendants to pay an amount equal to three times the amount of damages the United States has sustained as a result of Defendants' actions, plus the maximum civil penalty available for each violation of 31 U.S.C. §§ 3729 *et seq.*;

b. award Relator the maximum "relator's share" allowed pursuant to 31 U.S.C. § 3730(d) and/or any other applicable provision of law;

c. award Relator all costs and expenses of this action, including attorneys' fees, as provided by 31 U.S.C. § 3730(d) and any other applicable provision of law;

d. grant Relator and the United States of America such other and further relief as the Court may deem to be just and proper;

As to the TFCA and the TMFCA Claims:

e. award Relator and the State of Tennessee statutory damages in an amount equal to three times the amount of actual damages sustained by the State of Tennessee as a result of Defendants' actions, as well as the maximum statutory civil penalty for each violation by Defendants within the State of Tennessee, as provided by Tenn. Code Ann. §§ 4-18-103 and 71-5-182;

f. award Relator the maximum "relator's share" allowed pursuant to Tenn. Code Ann. §§ 4-18-104(g) and 71-5-183(c);

g. award Relator all costs and expenses associated with each of the pendent State claims, plus attorney's fees as provided pursuant to Tenn. Code Ann. §§ 4-18-104(g)(8) and 71-5-183(c);

h. grant Relator and the State of Tennessee such other and further relief as the Court may deem to be just and proper;

As to the Federal and State Retaliation Claims:

i. award Relator back and front pay in an amount to be determined at trial;

j. award Relator two times the amount of back pay that she would have had but for the retaliation, and interest on the back pay;

k. award Relator compensation for all special and compensatory damages, including emotional distress, sustained as a result of the retaliation and discharge, in an amount to be determined at trial, and litigation costs and reasonable attorneys' fees;

l. award Relator punitive damages for her claim under the TFCA, Tenn. Code Ann. § 4-18-105(c); and

m. grant Relator such other and further relief as the Court may deem to be just and proper.

JURY TRIAL DEMAND

Relator demands a trial by jury of all issues so triable.

Dated this 10th day of April, 2020.

/s/ Jerry E. Martin
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*Admission *Pro Hac Vice* to be filed